“AN OBSERVATIONAL STUDY ON THE FOLLOW UP OF PATIENTS WHO HAD INSERTION OF MIRENA “

DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS OF TAMIL NADU DR.M.G.R. MEDICAL UNIVERSITY FOR THE DEGREE OF M.S. BRANCH II (OBSTETRICS AND GYNAECOLOGY) EXAMINATION TO BE HELD IN APRIL 2013

CERTIFICATE

This is to certify that the dissertation entitled 'AN OBSERVATIONAL STUDY ON THE FOLLOW UP OF PATIENTS WHO HAD INSERTION OF MIRENA' is the original work of Dr. Latha Lakshmi.K, done under my guidance towards the M.S. Branch II (Obstetrics and Gynaecology) Degree Examination of The Tamil Nadu Dr. M.G.R Medical University, Chennai to be held in April 2013.

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ABSTRACT

TITLE OF THE ABSTRACT : 'An Observational study on the follow up of patients who had inserton of Mirena'

DEPARTMENT :Department of Obstetrics and Gynaecology

NAME OF THE CANDIDATE : Latha Lakshmi.K

DEGREE AND SUBJECT : M.S Branch II (Obstetrics and Gynaecology)

NAME OF THE GUIDE : Dr. Alice George, Professor, Department of O & G, UnitI

OBJECTIVES:

To follow up the patients, who had insertion of Mirena (Levonorgesterel intrauterine System) from 2007 and 2011, and to determine the effectiveness in decreasing the menstrual blood loss and pain after one year of insertion of Mirena ; To assess the quality of life at the end of one year after insertion and satisfaction among the patients.

METHODS:

The qualitative improvement in menorrhagia was assessed using the Uterine Fibroid Symptom and Health related Quality of life questionnaire (UFS-QoL); The general quality of life at the end of one year was followed up by the SF 36 questionnaire; The improvement in pain was assessed by the Visual analogue scale; The level of satisfaction was evaluated using the CGI- (global improvement item). Survival analysis was also done and the reason for removal compared by the Tarone-Ware method.

Statistical analysis was done by a paired t test for continuous variables and the significance calculated.

RESULTS:

The total number of insertions from 2007 to 2011 were 353, out of which 177 patient could only be followed up. The rate of voluntary removal of Mirena was 10.7% and the expulsion rate was 20%. 68.9% of patients showed symptomatic improvement; the symptom severity and the health related quality of life before and one year after insertion of Mirena, improved and was statistically significant ($p < 0.01$). Similarly the SF 36 showed high scores showing the better quality of life one year after insertion of Mirena.

There was statistically significant reduction in pain one year after insertion of Mirena ($p < 0.01$). 83.5% of patients were satisfied with Mirena; However the quantitative analysis of haemoglobin, before and one year after insertion of mirena, though showed some improvement, was not statistically significant.

INTRODUCTION

Abnormal uterine bleeding (AUB) is one of the most common reasons why women of the reproductive age group seek medical advice. Dysfunctional uterine bleeding, in the absence of a medical illness or pelvic pathology is responsible for almost half the cases of abnormal bleeding.

In the first place any organic cause should be ruled out and pregnancy should be excluded. Structural abnormalities such as leiomyoma, polyp or endometrial hyperplasia, can present as heavy menstrual bleeding. Adenomyosis and endometriosis predominantly present with dysmenorrhea, but can also present with menorrhagia.

There are various treatment modalities for abnormal uterine bleeding which includes the medical management with NSAIDs, tranexamic acid, progesterones, oral contraceptives, Danazol, GnRh analogues and Levonorgestrel-releasing intrauterine system.

Levonorgestrel-releasing intrauterine system(Mirena), was initially developed as a device for contraception , which does not suppress ovulation. It is a T shaped intrauterine device, which releases 20 microgms of levonorgestrel daily. It prevents endometrial proliferation and thereby reduces the duration and the quantity of bleeding.

Mirena was found to be superior to all other medical therapy and the blood loss reduced by almost 97% at the end of one year.

Compared to transcervical resection of the endometrium (TCRE), and balloon ablation, the success rate was higher in the resection and ablation group, but however the rate of satisfaction and change in the quality of life were similar. 64% of patients waiting for hysterectomy, cancelled hysterectomy when on levonorgestrel-releasing intrauterine system. Mirena was also found to be cost effective compared to hysterectomy. The surgical morbidity associated with hysterectomy is avoided, by using this hormone releasing intrauterine device.

As amenorrhea is expected in patients on Mirena, counselling should always include, about the advantages, side effects, the chances of expulsion of Mirena. The need for continuing some other mode of medical therapy along with Mirena, for the first few months should also be explained prior to insertion.

Mirena has a high efficacy in reducing the menstrual blood loss, without disturbing the fertility, and hence can be offered as a first line therapy for abnormal uterine bleeding. On the other hand hysterectomy is associated with a 100% success rate , in treating heavy menstrual bleeding and high patient satisfaction upto 95%, though there can be greater morbidity due to surgery itself.

Mirena can also be used in patients with adenomyosis and endometriosis, and the principle behind is probably the atrophy of the endometrial glands and extensive transformation of the decidua , caused by the chronic exposure of the endometrium to

progesterones. It is successful in the patients presenting with menorrhagia of unknown reason.

As quantitative assessment is not very practical , it is possible to analyse the qualitative improvement in the life of patients on Mirena. So the different methods used to assess the qualitative improvement includes, the fibroid related symptom improvement and health related quality of life improvement assessment , the SF36 scoring for the improvement in the general health after one year of insertion, the improvement in the pain scale and also the level of satisfaction scale.

The above aspects were followed up in the patients who had insertion of Mirena from 2007 to 2011, our hospital, in the department of obstetrics and gynaecology, Christian Medical College and Hospital, Vellore.

AIMS AND OBJECTIVES

1. To follow up patients who had Levonorgestrel releasing intrauterine system (Mirena) inserted from 2007 to 2011 (5 years), in the Department of Obstetrics and Gynaecology, Christian Medical College and Hospital, Vellore.

2. To determine the effectiveness of Levonorgestrel releasing intrauterine system (Mirena), in decreasing the menstrual blood loss, at the end of one year after insertion.

3. To determine the effectiveness of Levonorgestrel releasing intrauterine system (Mirena) in those with dysmenorrhea and dyspareunia, at the end of one year after insertion.

4. To study the health related quality of life , at the end of one year after insertion.

5. To assess the level of satisfaction among those using Levenorgestrel releasing intrauterine system.
6. To do survival analysis, and assess the voluntary removal and expulsion rates.

REVIEW OF LITERATURE

Abnormal uterine bleeding affects 10 – 30% of women of the reproductive age group and about 50% of women in the perimenopausal age group. It accounts for 15% of office visits and almost 25% of gynecologic operations.

The length of one menstrual cycle is 28 days and the average duration is 4 days and an average blood loss of 35 ml per cycle.

Table 1: **The characteristics of the normal menstrual cycle** (1)

	Average	**Range**	**Abnormal**
Cycle length	28 d	21-35 d	<21 or > 35 d
Duration	4 d	1-8 d	>8 d
Blood loss	35 ml	20 – 80ml	>80 ml

PATTERNS OF ABNORMAL UTERINE BLEEDING

MENORRHAGIA

The Royal college of Obstetricians and gynaecologists, defines menorrhagia as "heavy cyclical bleeding over several consecutive cycles" (2). Blood loss greater than 80 ml per cycle, is the accepted definition as far as heavy menstrual bleeding is concerned.

Menometrorrhagia is prolonged and irregular bleeding.

Polymenorrhea is bleeding at < 21 - day intervals

POSTCOITAL BLEEDING

It is genital tract bleeding after intercourse. Cervical cancer, polyps, ectropion or genital tract infection, can clinically present as bleeding . All women with postcoital bleeding should be referred for colposcopy, inspite of a recent negative smear test.

INTERMENSTRUAL BLEEDING

Other than during menstruation or following intercourse if a woman has bleeding arising from the genital tract, then it is termed so.

POSTMENOPAUSAL BLEEDING

This is defined as genital tract bleeding occurring more than 12 months after the last menstrual period. The term menorrhagia generally points to the uterine source of bleeding .

The terms postcoital bleeding, intermentstual bleeding and postmenopausal bleeding describe only clinical terms used for the presentation and not refer to a specific site, from where the bleeding occurs.

POSSIBLE SOURCES OF BLEEDING TO BE CONSIDERED ARE:

1. Whole of the Genital tract
2. Gastrointestinal tract
3. Urinary tract

THE MECHANISMS OF MENSTRUATION -THE CURRENT CONCEPTS :

Menstruation is the process whereby the superficial or functionalis layer of the endometrium lining the uterine cavity disintegrates and is removed from the uterine lumen towards the end of the luteal phase of a non- pregnant cycle.

The 90^{th} percentile for blood loss during menstruation was found to be 80 ml, by carefully measuring total menstrual loss, and that anaemia was increased significantly in

women who lost greater than 60 ml. Loss of more than 80 ml per menstrual episode, on the other hand was defined as menorrhagia.

When the patient perception of the quantity of loss is compared to objective measurement, there are often significant discrepancies. 25% of women whose measured blood loss was normal , considered it to be "heavy", and 40% of those with documented excessive flow(i.e. > 80 ml) described their loss as "light".(3)

Table **2: Menstrual blood loss- Random population studies**

	Hallberg et al (1966)	**Cole et al (1971)(4)**
Mean blood loss(ml)	43.4 ± 2.3	37.5±3.3
Median loss(ml)	30.0	27.6
Range	10.4 – 83.9	0.1 – 280
Loss > 60 ml	19.0%	20.7%
Loss > 80 ml	11.0%	9.5%

MECHANISMS OF MENSTRUATION:

Menstruation is the culmination of the changes in both the cellular and vascular architecture of the endometrium which follow the withdrawal of progesterone (and oestrogen) at the end of the secretory phase.

The major cellular components that contribute to menstruation are the stromal and vascular components. The week prior to menstruation stromal edema accompanies decidualization, growth of the large blood vessels and intense coiling of the spiral arterioles.

Two to six days before bleeding begins the stromal oedema shrinks, with associated increase in spiral arteriolar coiling and vascular stasis. This is followed by a period of vasodilation and perivascular bleeding from the wall of a capillary or arteriole, and then some 24 hours later by intense vasoconstriction and tissue necrosis. 70% approximately is lost through the vessel wall, 5% by diapedisis and 25% by reflux from veins through the areas where there were previous breaks.

There are different hypothesis that explains menstruation.

1. The Vasoconstrictor theory:

   This suggest

   (a) the existence of pressor agents which play a role in vascular stasis,

   (b) protection against excessive blood loss

Arachidonic acids is derived from the phospholipids present in the cell membranes. Prostaglandins(PG), on the other hand are synthesized from arachidonic acid.

Prostaglandin (PG) :

- Not stored in tissues
- Released locally and act locally
- Rapid metabolism, and therefore a short half life
- Have powerful stimulating properties of the vascular and smooth muscle .

Thromboxane A2 is a vasoconstrictor and inhibitor of platelet aggregation.

PGI2 is a vasodilator and inhibitor of aggregation

PGF2 alpha is a vasoconstrictor and smooth muscle stimulator.

PGE is a vasodilator

The role of PGs in menstruation was summarized by Baird et al (5) in 1996. PG occurs in the menstrual fluid and endometrium in high concentrations, and oestrogens and progestogens influence their synthesis. PGF2alpha caused menses and an increase in the uterine contractility; COX-2 inhibitors reduces blood loss during menstruation and inhibits increased uterine contractility associated with dysmenorrhoea.

The Inflammatory hypothesis

Inflammation is characterized by:

1. Tissue oedema
2. Inflammatory cell recruitment
3. Pro-inflammatory cytokine release

Finn, postulated that menstruation could be regarded as an inflammatory process(6), as there is a dramatic increase in the numbers of lymphomyeloid cells identified in the endometrium, prior to menstruation.

The endometrial granular lymphocytes increase from proliferative to secretory phase. Other inflammatory cell found in substantial numbers includes eosinophils, macrophages and neutrophils, whereas T and B cells present, are in low numbers. Steroid hormones possibly modulate migratory cell influx via the chemokine action.

Neither oestrogen receptors (ER) nor progesterone receptor (PR), have been found in the leucocytes , in the human endometrium, and so their effects on leukocytes may be only indirect.

TISSUE REPAIR

As early as 36 hours after the onset of bleeding due to menstruation, repair of the endometrium begins. However the desquamation is still in progress, due to the very focal nature of the degradative and repair processes (7).Regeneration is complete by 140 hours.

The menstrual fluid is composed of autolysed endometrium rich in inflammatory exudates, RBCs and proteolytic enzymes(8). Plasminogen has fibrinolytic action, that prevents clotting of menstrual fluid and facilitates the expulsion of the degenerated tissue. The local balance between the fibrinolysis and clotting, controls the amount of bleeding.

Table 3: **CAUSES OF ABNORMAL UTERINE BLEEDING**

Pelvic	Uterine fibroids Adenomyosis Endometrial polyps Pelvic infection Endometrial hyperplasia Endometrial adenocarcinoma Intra uterine device Uterine vascular malformations Myometrial hypertrophy
Systemic	Coagulation disorders(thrombocytopenia, Von Willebrand disease) Hypothyroidism, SLE, Chronic liver failure
Functional	Dysfunctional uterine bleeding

Table 4: MEDICAL DISEASE ASSOCIATED WITH MENORRHAGIA

ENDOCRINE DISEASE	Thyroid dysfunction Pituitary/Adrenal abnormalities
HAEMATOLOGICAL DISEASE	Coagulation disorders Platelet abnormalities Sickle cell anemia
AUTO-IMMUNE DISEASE	SLE
HEPATIC, RENAL AND CARDIAC DISEASE	Liver disease Renal disease Cardiac disease
METABOLIC DISEASE	Gaucher's disease

GENITAL TRACT BLEEDING- NON – UTERINE CAUSES:

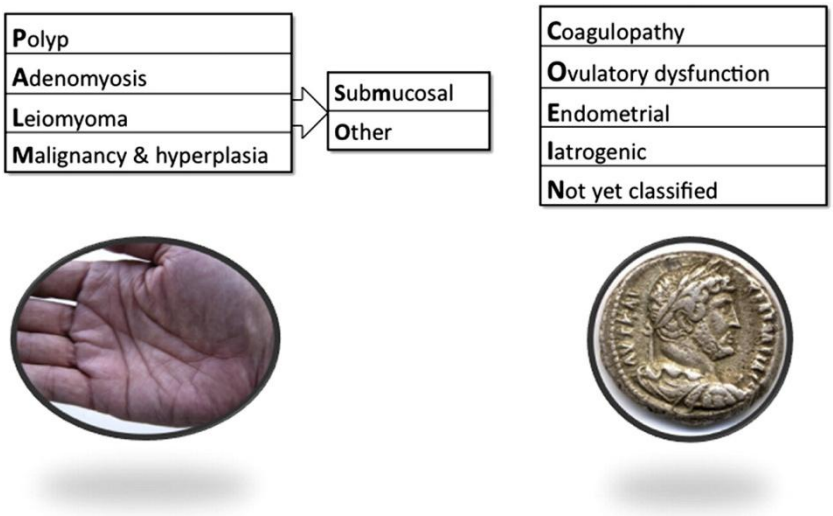
1. Atrophic vaginitis
2. Vulval causes
    i. Vulval intra epithelial neoplasia
    ii. Carcinoma vulva
    iii. Skin lesions
3. Lesions in the vagina
4. Trauma
5. Foreign body

FIGO CLASSIFICATION SYSTEM (PALM-COEIN) FOR ABNORMAL UTERINE BLEEDING (9)

This is an universally accepted system of classification . This new classification including contributions from an international group of clinician-investigators from six continents and over 17 countries, proposes a new system for the classification of abnormal uterine bleeding.

There are nine main categories, are arranged according to the acronym PALM-COEIN. **P**olyp; **A**denomyosis; **L**eiomyoma; **M**alignancy and **H**yperplasia. **C**oagulopathy; **O**vulatory dysfunction; **E**ndometrial; **I**atrogenic; **N**ot yet classified.

Figure 1: **FIGO CLASSIFICATION OF AUB**



The PALM entities are structural, discrete, measured visually by imaging or by histopathology; The COEIN group is non structural; related to those not defined by imaging or histopathology.

The term "DUB", used earlier, for diagnosis in the absence of other systemic or locally definable structural cause, should be abandoned and should not be included in the system.

POLYP(AUB-P)

This comprises a variable vascular, glandular, and fibromuscular and connective tissue component and are often asymptomatic, but can contribute to AUB (10). Usually, they are benign, but a minority may have atypical or malignant features.(11)

ADENOMYOSIS (AUB-A)

Prevalence varies from 5% to 70% (12). The relationship between adenomyosis and the genesis of abnormal bleeding is unclear. It is proposed that sonographic criteria for adenomyosis comprises the minimum requirements for assigning an individual the diagnosis of adenomyosis in the PALM-COINE classification(13). The sonographic appearance is partly related to the presence of endometrial tissue in the myometrium and hypertrophy.

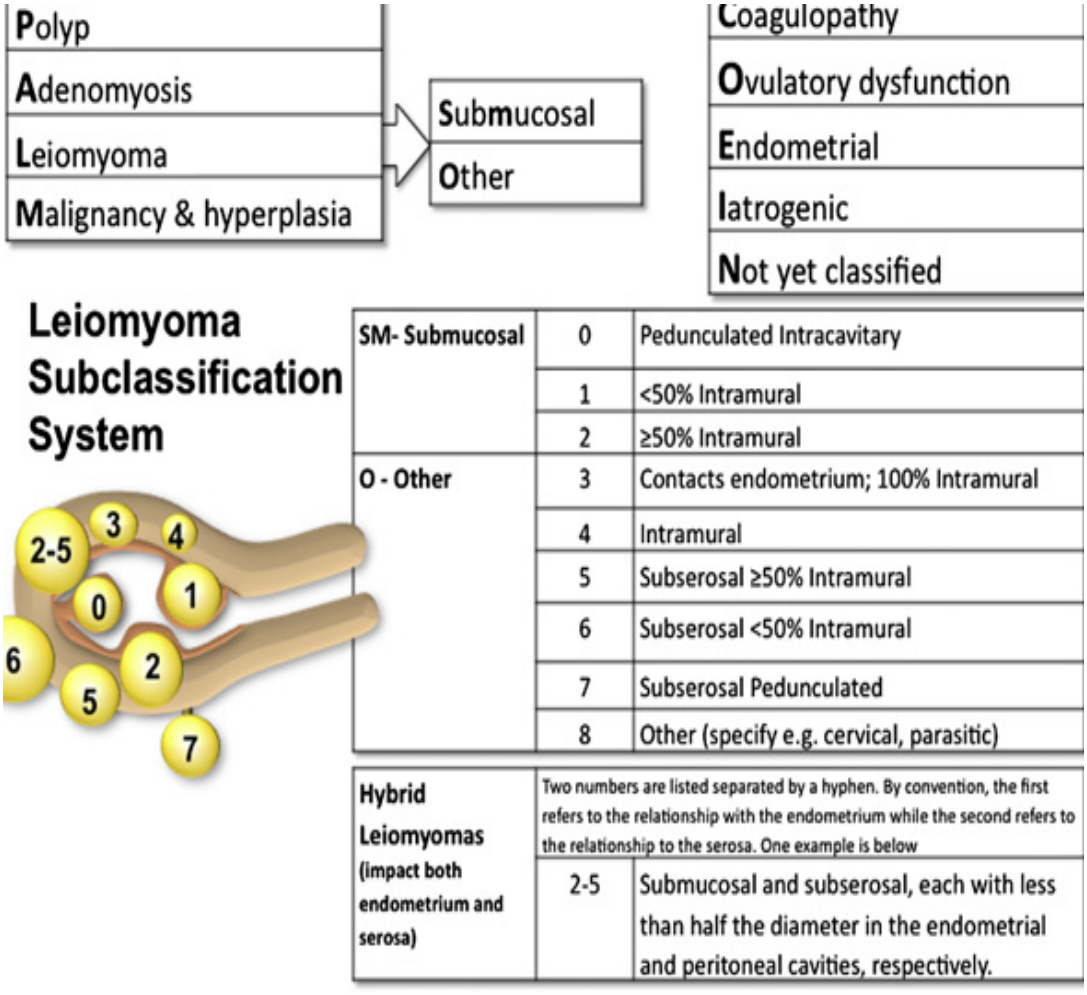
LEIOMYOMA (AUB-L)

The prevalence is upto 70% in Caucasians. Due to the spectrum of size and location and the variable number of lesions in a given uterus it has a separate categorization in the system. Many leiomyomas are asymptomatic. Several issues like, the relationship of the leiomyoma to the endometrium and serosa; the uterine location of the leiomyoma (upper segment, lower segment; cervix, anterior, posterior, lateral); the size of the lesions; the number, were considered in the classification system.(14)

The primary classification system reflects only the presence or absence of one or more leiomyomas; The seconday system distinguishes leiomyomas involving the endometrial cavity(submucousal) from others, as submucousal is considered most likely to contribute to the genesis of AUB.

The tertiary classification system is a design for subendometrial or submucosal leiomyomas.

Figure 2 : **Leiomyoma subclassification**



SM- Submucosal	0	Pedunculated Intracavitary
	1	<50% Intramural
	2	≥50% Intramural
O - Other	3	Contacts endometrium; 100% Intramural
	4	Intramural
	5	Subserosal ≥50% Intramural
	6	Subserosal <50% Intramural
	7	Subserosal Pedunculated
	8	Other (specify e.g. cervical, parasitic)
Hybrid Leiomyomas (impact both endometrium and serosa)	Two numbers are listed separated by a hyphen. By convention, the first refers to the relationship with the endometrium while the second refers to the relationship to the serosa. One example is below	
	2-5	Submucosal and subserosal, each with less than half the diameter in the endometrial and peritoneal cavities, respectively.

The size of the uterus, single longest measurement, the location and estimated number of leiomyomas are not included in the classification.

MALIGNANCY AND HYPERPLASIA(AUB-M)

The potential causes of AUB, include atypical hyperplasia and malignancy , and this should be considered in the women of reproductive age group.

COAGULOPATHY(AUB-C)

Von Willebrand disease(15), is the systemic disorders of hemostasis, diagnosed in approximately 13% of women with HMB. Some women may require chronic anticoagulation as an intervention, required to preserve life; these patients on these drugs present with AUB, which may or may not respond to oral medications.

OVULATORY DYSFUNCTION (AUB-O)

Any disorder of ovulation, can present as menstrual abnormalities – which could range from amenorrhea, to extremely HMB requiring intervention. Ovulatory disorders (endocrinopathies) like polycystic ovary syndrome, thyroid disorder which includes hypothyroidism, hyperprolactinemia, mental stress, obesity, anorexia, weight loss or extreme exercise .

ENDOMETRIAL (AUB-E)

There may be a primary disorder of "hemostasis", where evidence has demonstrated deficiencies in local production of vasoconstrictors such as endothein-1 and prostaglandin F2α. Accelerated lysis of endometrial clot because of excessive production of plasminogen activator has also been demonstrated (16).

Increased production of substances that promote vasodilatation, e.g. PGE2 and Prostacyclin I_2 has been known to cause increased uterine bleeding (17).

Retrospective evaluation does not reveal any relationship of endometritis with AUB, but there are data indicating a relationship between subclinical Chlamydia trachomatis and AUB (18).

IATROGENIC (AUB-I)

This includes

a. Intrauterine systems, either medicated or inert.
b. Pharmacologic agents that directly impact the endometrium.
c. Interference with blood coagulation mechanisms.
d. Those influencing the systemic control of ovulation.

Episodes of break through bleeding are related to reduced circulating gonadal steroid levels, due to compliance issues, such as missed, delayed or erratic use of pills. Reduced levels of estrogens and progestins , due to use of anticonvulsants and antibiotics (e.g. rifampicin/griseofulvin), can also cause AUB(19).

Women on Levonorgestrel-releasing intrauterine system (LNG – IUS), experience unscheduled vaginal spotting in the first 3 -6 months (20).

In a UK study, 10% of new users, of the LNG-IUS, ceased use by the end of the first year because of bleeding complaints (21).

Any agent that impacts serotonin uptake is a candidate for causing ovulatory dysfunction and that result in irregular bleeding (e.g. Tricyclic antidepressants)

Anticoagulants like warfarin and heparin, impairs the formation of an adequate "plug"or clot with the vascular lumen, and hence conributes to HMB.

NOT YET CLASSIFIED (AUB-N)

Entities such as endometritis, arteriovenous malformations, myometrial hypertrophy need further evidence for classification, into a particular category.

EVALUATION OF ABNORMAL UTERINE BLEEDING

There may be multiple factors contributing to the AUB, and hence, a patient presenting with the symptoms should be diligently investigated.

a. General assessment
b. Rule out pregnancy
c. Evaluate anaemia
d. Rule out disorders of ovulation
e. Screening for systemic disorders if required
f. Rule out anticoagulation therapy.
g. Adequate endometrial sampling, if suspicious of atypical hyperplasia or carcinoma.
h. Abdominal examination
i. Palpate to rule out fibroid uterus

    A. Examination of the vulva and vagina for any gross pathology
    B. Speculum examination – To exclude cervical polyp, tumour and to take pap smear.
    C. Bimanual pelvic examination

INVESTIGATIONS

The latest guidance from the National Collaborating Centre for Women's and Children's health states that, " if the history is suggestive of menorrhagia, without suspicion of any structural or histological abnormality, treatment can be commenced; whereas if the treatment option is levonorgestrel-releasing intrauterine system, other investigations should be performed" (22).

The initial assessment requires the patient to have a combination of unpredictability, excessive duration, abnormal volume, or abnormal frequency of menses, for atleast the previous three cycles.

A. **Blood tests** –

Full blood count , which includes platelets.

Serum ferritin level if any doubt about iron deficiency anaemia (23).

Thyroid function tests – if history/examination suggestive

Coagulation profile if history of bleeding disorder

(puberty menorrhagia or family history if present)

B. **Assessment of Uterine Cavity** –

a. Ultrasound

- This is the first line diagnostic tool to identify structural abnormality
- Helps to assess size/number/location of fibroids. Transvaginal ultrasound results in high quality image and improves predictive value(24).

- Saline infusion sonography detects submucous fibroids. Endometrial thickness <5 mm in postmenopausal and Endometrial thickness between 10 – 12 mm in premenopausal needs further evaluation(25).

b. Endometrial biopsy

- Endometrial sampling is considered for all women with ultrasonic abnormality and those with persistent menorrhagia(26).
- Outpatient biopsy has high accuracy and the Pipelle endometrial sampler is a preferred device.
- Majority of women investigated for Menorrhagia have 'normal' endometrium, and so been labeled to have a functional disorder.

c. Dilatation and curettage

No longer has a role.

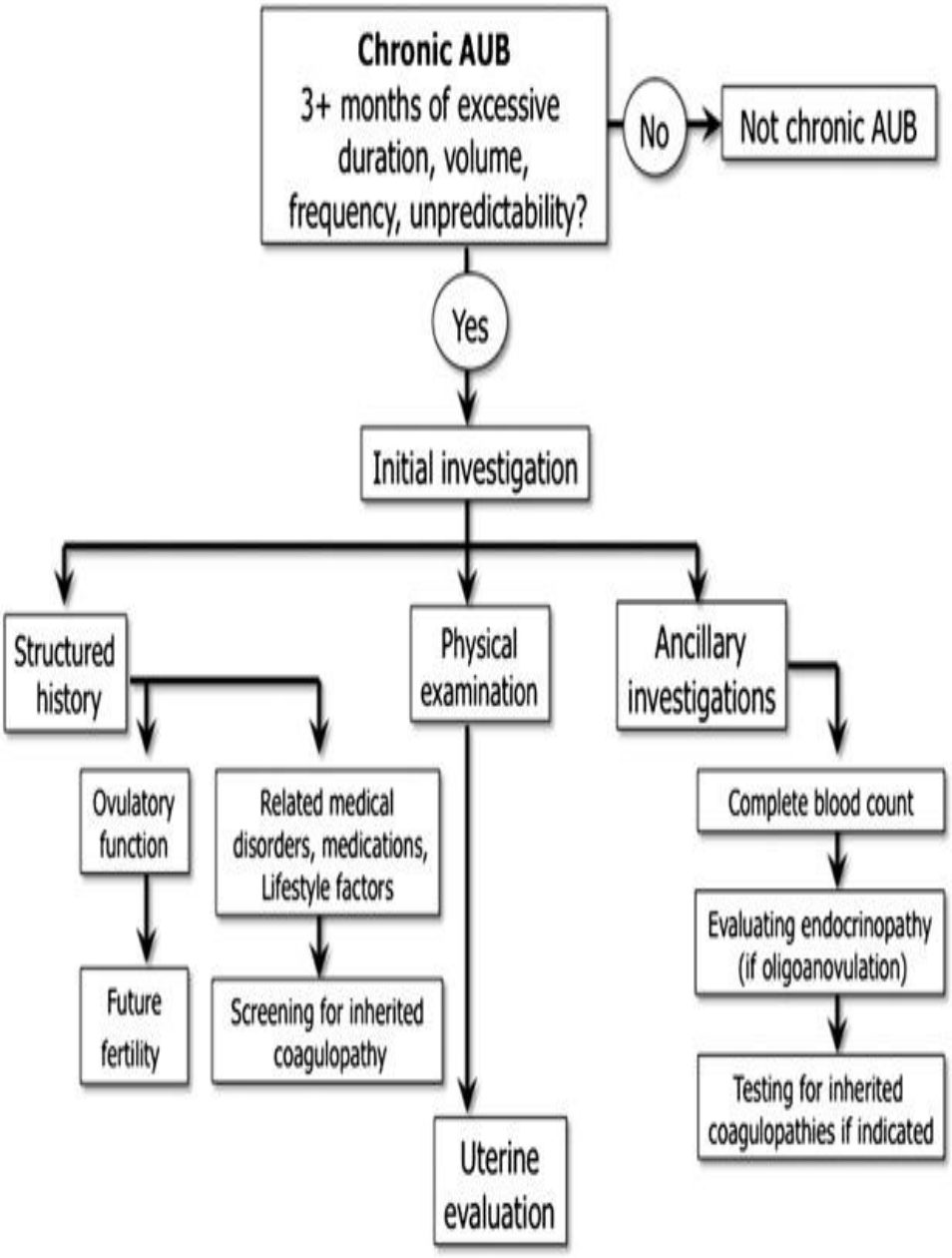
d. Hysteroscopy

- Better than ultrasound , at identifying polyps.
- Performed in the outpatient room, only if ultrasound scan is inconclusive.
- Normally more painful than transvaginal ultrasound.

e. Magnetic resonance imaging

No advantage over ultrasound and hence not done routinely.

Figure 3: **Evaluation of Chronic AUB**



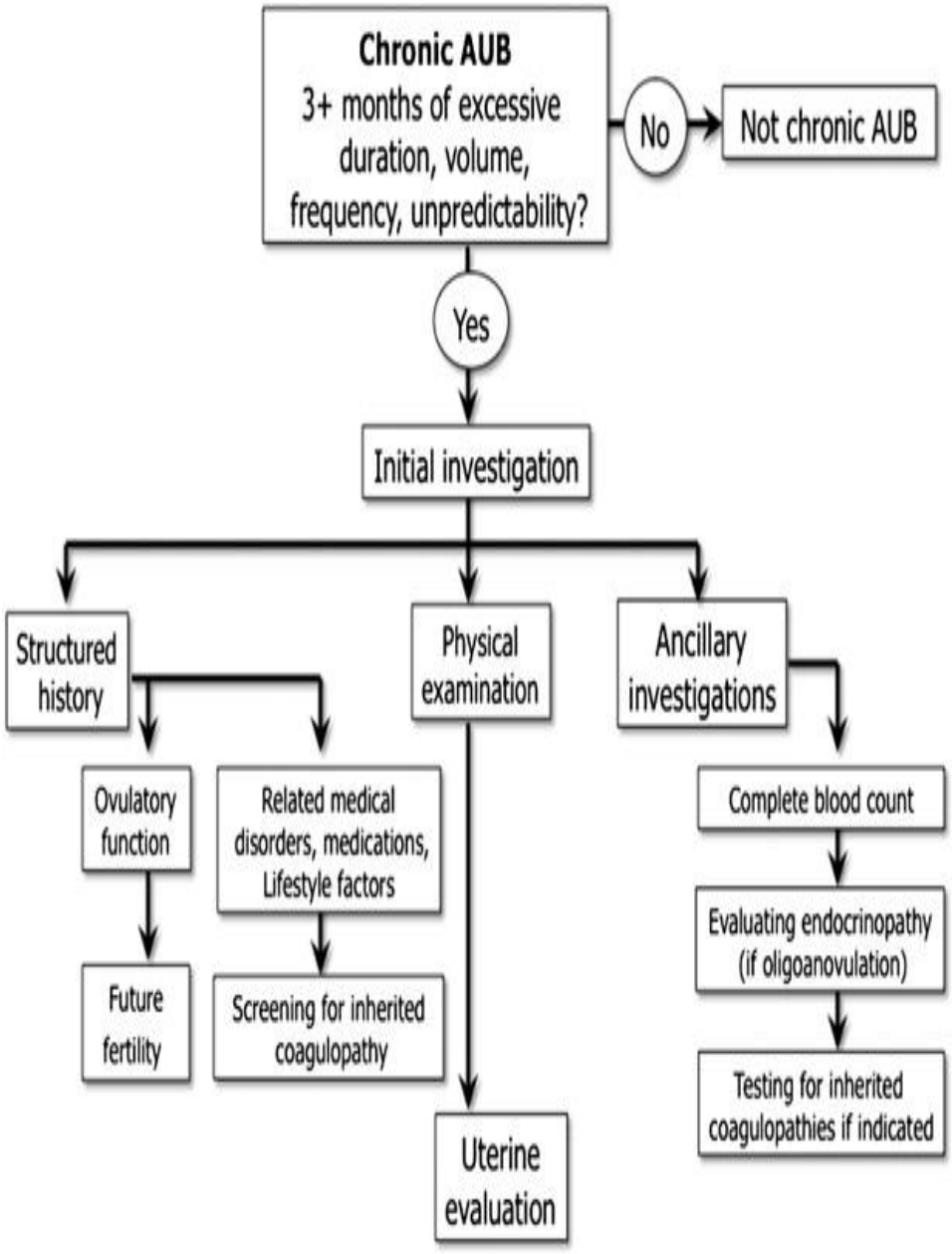
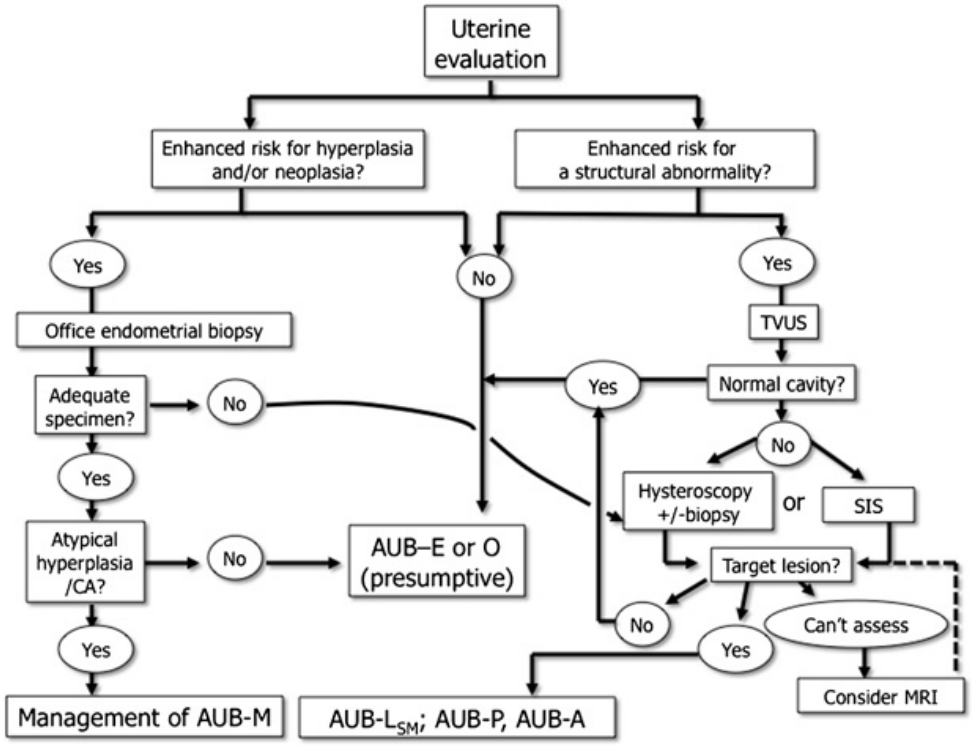

Chronic AUB
3+ months of excessive duration, volume, frequency, unpredictability?
No
Not chronic AUB
Yes
Initial investigation
Structured history
Physical examination
Ancillary investigations
Ovulatory function
Related medical disorders, medications, Lifestyle factors
Future fertility
Screening for inherited coagulopathy
Uterine evaluation
Complete blood count
Evaluating endocrinopathy (if oligoanovulation)
Testing for inherited coagulopathies if indicated

Figure 4: **Uterine Evaluation in AUB**



The uterine evaluation is in part, guided by a good history, other elements of clinical situation, such as age, chronic ovulatory disorder or presence of other risk factors for endometrial hyperplasia or malignancy. Evaluation of the uterus should include imaging, atleast with a screening transvaginal ultrasound examination(TVUS).

Even in ideal circumstances, TVUS is not 100% sensitive, as polyps and other small leisions may not be picked up(27).

MANAGEMENT OF ABNORMAL UTERINE BLEEDING

The treatment of menorrhagia may be medical or surgical. In one review 60% of women referred to the hospital with menorrhagia, had hysterectomy within 5 years(28)

MEDICAL MANAGEMENT:

More than 90% of blood loss usually occurs in the first 3 days of menstruation. So treatment protocol can be either the first few days, which has an advantage of restricting medications only to those days of heavy flow. Anemia should also be adequately treated. The three treatment regimen which fit into this are prostaglandin synthetase inhibitors, tranexamic acid and ethamsylate.

a. Hormonal treatments:
    - Synthetic progestogens
    - Combined oral contraceptive pill
    - Danazol
    - Gonadotrophin- releasing hormone(GnRH) analogue.
    - Prostaglandin synthetase inhibitors
    - Inhibitors of fibrinolysis
    - Reducers of platelet fragility.

SYNTHETIC PROGESTERONES

This is the most popular drug prescribed in the United Kingdom and New Zealand, for menorrhagia(29).

The first report of its use was in 13 women, by Bishop and de Almeida, 1960, and they reported subjective improvement in menstrual blood loss in 34 out of 52 treatment cycles, and then this regimen was universally adopted.

A route of administration included, intermittent luteal phase oral administration to intramuscular injection to continuous local administration via intrauterine device. Each of these have different efficacy.

Cyclical administration

Administered usually in the luteal phase of the cycle. Study of norethindrone 10 mg per day 15 to 25 , showed no significant reduction in menstrual blood loss (30).

British investigators evaluated norethindrone in a dose of 10 mg/day from day 19 to 26 and found an increase in bleeding volume by 20% compared to decrease of 45% in the Tranexemic group(31).

The Cochrane meta-analysis concluded that luteal phase progestins were less effective than tranexamic acid, danazol, progestin- releasing IUD(32). A randomized clinical trial , compared use of progestin releasing intrauterine device with oral progesterone from day5 to day 26 and found a 87% reduction in blood loss in the oral group, but the reduction in the volume was less, compared to the ID group(33). In another RCT comparing the same, both were effective in the treatment of menorrhagia, but intrauterine levonorgesterel , had higher satisfaction and continuation of treatment (76% vs 22%) and hence an effective alternative(34).

Anovulatory women were more likely to be satisfied with the use of cyclical progestins, than those with ovulatory cycles.

CONTINUOUS SYSTEMIC ADMINISTRATION

Studies of depoprovera demonstrate that by 1 year, 80% become amenorrheic(35). There are no published data evaluating Depovera in patients with menorrhagia.

CONTINUOUS LOCAL ADMINISTRATION

Progestin-impregnated intra uterine device is in use for nearly 3 decades(36). For women in the reproductive age group, Levonorgestrel intra-uterine system is one of the most acceptable medical treatments for menorrhagia

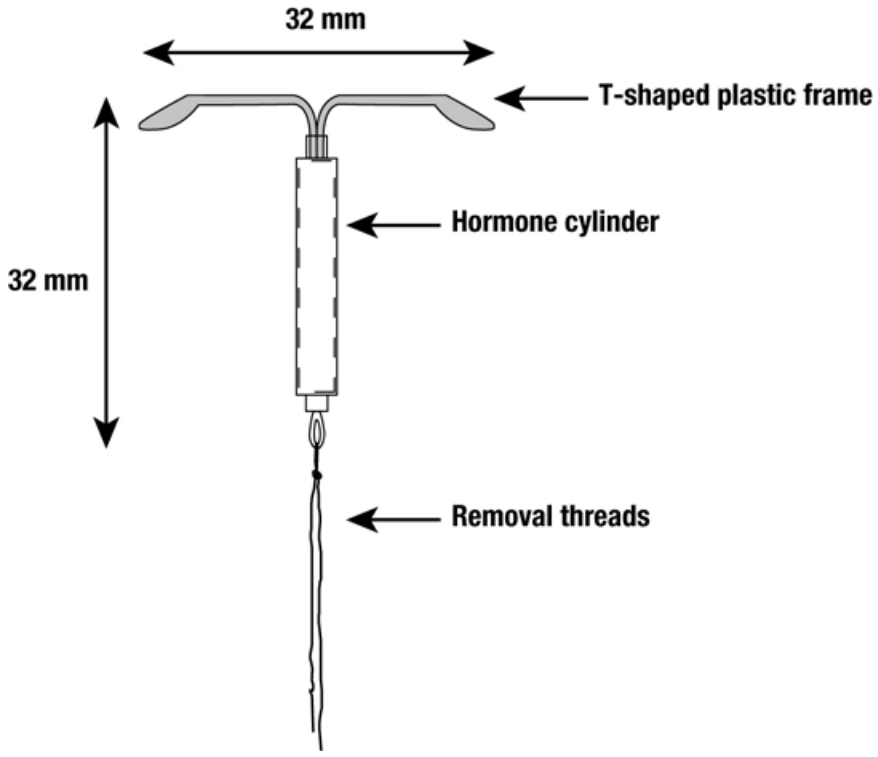
Reduces referrals to specialists and decreases the need for operative gynaecological surgery.

MIRENA (LEVONORGESTREL – RELEASING INTRAUTERINE SYSTEM)

Mirena LNG-IUS (levonorgestrel-releasing intrauterine system) consists of a T-shaped polyethylene frame (T-body) with a steroid reservoir (hormone elastomer core) around the vertical stem.

The reservoir consists of a white or almost white cylinder, made of a mixture of levonorgestrel and silicone , containing a total of 52 mg levonorgestrel. The reservoir is covered by a semi-opaque silicone (polydimethylsiloxane) membrane. The T-body is 32 mm in both the horizontal and vertical directions. The polyethylene of the T-body is compounded with barium sulfate, which makes it radiopaque. A monofilament brown polyethylene removal thread is attached to a loop at the end of the vertical stem of the T-body.

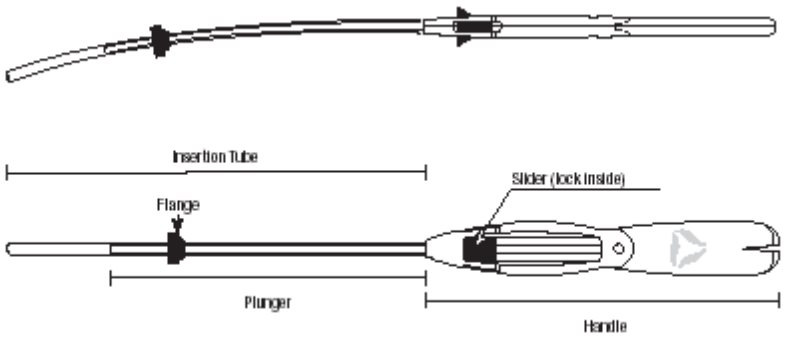
Figure 5 : **Mirena**



INSERTER

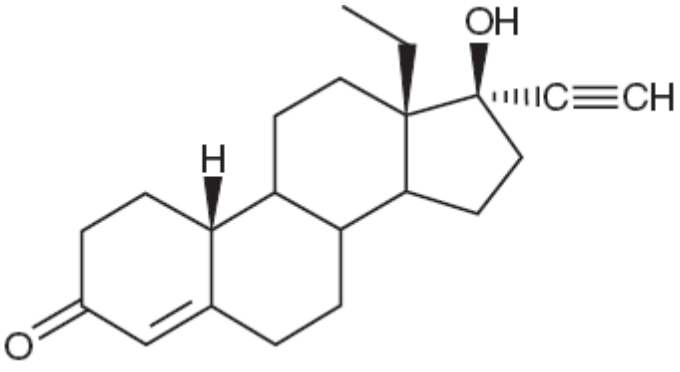
It is in a sterile pack which is discarded after insertion. Mirena is packaged sterile within an inserter. The inserter, which is used for insertion of Mirena into the uterine cavity, consists of a symmetric two-sided body and slider that are integrated with flange, lock, pre-bent insertion tube and plunger. Once Mirena is in place, the inserter is discarded.

Figure 6: Diagram of Inserter



Levonorgestrel USP, (-)-13-Ethyl-17-hydroxy-18,19-dinor-17α-pregn-4-en-20-yn-3-one, the active ingredient in Mirena, has a molecular weight of 312.4, a molecular formula of C21H28O2, and the following structural formula:

Figure 7: **Levonorgestrel**



Pharmacology:

The initial release is 20µ gms per day till 5 years. This rate decreases to half after 5 years (37).

There is a rapid absorption of locally released levonorgestel from the uterine cavity, via the capillary network in the basal layer of the endometrium, into the systemic circulation.

Levonorgestrel can be detected within 15 minutes after insertion, reaching maximum plasma levels within a few hours. The intrauterine concentration are 1000 times higher than with a levonorgestrel subdermal implant(38).

Mirena has mainly local progestogenic effects in the uterine cavity.

Morphological changes of the endometrium, include

a)Stromal pseudodecidualization,

b) Glandular atrophy,

c) Leukocytic infiltration, and

d) Decrease in glandular and stromal mitoses.

e) Alteration in the cerivical mucus and uterotubal fluid

f) Inhibits sperm migration

g) Adverse effect on the sperm motility an function inside the genital tract, preventing fertilization.

h) Vascular changes – Decrease in mean vascular density and increase in mean vessel area(39).

i) Ovulation is suppressed by reducing the pre-ovulatory surge in luteinizing hormone. 45% of the cycles were ovulatory at the end of one year. Most cycles become ovulatory from the second year onwards, to reach 75% at the end of 4 years. Presence or absence of menstrual bleeding does not reflect ovarian activity.

POST INSERTION EFFECTS:

Women inserted with IUS, frequently complain of menstrual disturbance. Prolonged bleeding for >8 days is seen in 17% of women in the first month of use, falling to 3% at the end of 3 months. It takes 6 months on an average to settle in women with heavy flow(40).

Amenorrhea is seen in 17% at the end of one year, increasing to 60% in long term users(41). One to two women out of 100 women discontinue IUS because of progestogenic symptoms(42).

ADVERSE EFFECT(42,43).

1. Uterine and vaginal bleeding (including spotting, irregular bleeding, heavy bleeding, oligomenorrhea and amenorrhea)
2. Ovarian cysts
3. Abdominal/pelvic pain
4. Vaginal discharge
5. Nausea/ Headache/ Nervousness.
6. Vulvovaginitis
7. Dysmenorrhea/ Back pain
8. Weight increase
9. Breast pain/tenderness
10. Acne
11. Decreased libido /Depressed mood
12. Class II Hypertension

REMOVAL OF MIRENA:

Indications for removal of mirena include-

- Acquired immune deficiency syndrome (AIDS)
- Sexually transmitted disease
- Pelvic infection; endometritis
- Symptomatic genital actinomycosis
- Intractable pelvic pain
- Severe dyspareunia
- Pregnancy
- Endometrial or cervical malignancy
- Uterine or cervical perforation

Mirena is preferably removed at the time of a menstrual period, but if removed otherwise, should be advised to avoid sexual intercourse for 7 days before removal(44).

CLINICAL STUDIES ON INTRA UTERINE LEVONORGESTREL DEVICE

1) **Menorrhagia** (Including Adenomyosis and Fibroid related)

In 1982, Heikkila et al showed that serum ferritin levels improved in IUS users, with normal menstrual blood loss(45).

Haemoglobin was also found to increase in women with menorrhagia(46).

In 1990, 20 women with menorrhagia, on IUS, showed a reduction in blood loss by 86% in 3 months and 97% in 12 months(47).

Table 5: In 1991, Milsom et al(48), compared the reduction of menorrhagia and found

At 3 months	NSAID	Antifibrinolytic	IUS
Reduction in blood loss	20.7%	44.4%	81.6%

At the end of one year, there was a 95.8% reduction in menstrual blood .Amenorrhea was found in 35% of women, at the end of 24 months(49).

Compared to Mefenemic acid(NSAID), LNG reduced the blood loss to just 5 ml in women with idiopathic menorrhagia(50).

Table 6: Comparison between the IUS and norethisterone (51), group showed:

In 3 cycles	IUS group	Norethisterone group
Reduction in menstrual blood flow	94%	87%
Wish to continue treatment	76%	22%

Table 7: Cancellation of major surgery was noticed in 6 months, after insertion(52):

At 6 months	IUS	Controls
Cancellation of surgery	64.3%	14.3%

In a 5 year follow of patients, with IUS, 42% of patients on IUS ultimately had hysterectomy. However, use of IUS was cheaper than hysterectomy(53). Health related quality of life and psychosocial well being was the same in both the IUS and the hysterectomy groups.

Table 8: Minimally invasive surgery like Endometrial resection or ablation was compared with IUS use(54).

At 12 months of use	IUS	Endometrial resection
Pictorial blood loss assessment chart(PBAC)	79% reduction	89% reduction
Amenorrhea/infrequent bleeding	65%	71%
Satisfaction	High	High

Between Thermal balloon endometrial ablation and IUS, both were found to be equally effective(55).

Cochrane systematic review concluded hysterectomy reduced menstrual bleeding at one year, more than the other medical treatments, but IUS, was found to be equally effective in improving the quality of life(56).

IUS has an effect on the haemostatic and fibrinolytic inhibitor systems in women with menorrhagia and demonstrates high expression of fibrinolytic inhibitors and urokinase-type plasminogen activator in the endometrium, without altering the systemic haemostasis. Therefore IUS is used to treat inherited bleeding disorders(57).

In women with fibroid related problems(58), LNG-IUS

- Reduces the need for surgery
- Reduces blood loss
- Causes rise in serum ferritin
- Causes rise in haemoglobin
- No significant effect on the reduction in uterine size and fibroid volume.

In women with Adenomyosis related menorrhagia, IUS may reduce menstrual blood loss significantly, but more studies are required(59).

2. Endometriosis

About 21% of women being investigated for infertility, are found to have endometriosis. However atleast 50% of women in the United Kingdom complain of moderate dysmenorrhea.

Table 9: **On following up the insertions of IUS(60):**

In 36 months	**Before insertion of IUS**	**After insertion of IUS**
Dysmenorrhea	60%	29%

IUS improved the disease staging(61), and reduced pain in those with Rectovaginal endometriosis(62).

Table 10: In those women, who had IUS inserted post operatively, after conservative surgery for endometriosis(63),

12 months post op.	**Inserted IUS**	**Expectant treatment**
Recurrence of moderate to severe dysmenorrhea	10%	45%

Comparing women with IUS and depot gonadotrophin-releasing hormone analogue, for controlling pain related to endometriosis, there was a rapid improvement in those with severe endometriosis, but women with IUS had a higher bleeding score throughout 6 months of the study, but the quality of life was similar, in both the groups(64).

How does IUS improve the endometriosis- related pain? (65**).**

- Causes alteration in the production of local tissue factors
- Blockage of endometrial DNA synthesis

- Blockage of mitotic activity
- Endometrial atrophy
- Higher level of peritoneal fluid levels of levonorgestrel
- Anovulation at 3 months, till atleast 12 months, after which it becomes ovulatory.

Long term randomized controlled trials are required to prove the additional advantages of a treatment lasting for 5 years, with one device.

3. Endometrial Hyperplasia

Studies show that IUS would cause regression of endometrial hyperplasia. First study was published in 2003, where IUS caused complete regression of endometrial hyperplasia(66). Cell apoptosis and downregulation of oestrogen and the progesterone receptors was found to be the mechanism of action in women with endometrial hyperplasia(67).

In the treatment of early stage I endometrial cancers, caution is advised, as complete histological regression is not seen in all treated(68). Hence it is important to investigate women with persistent heavy menstrual bleeding appropriately.

4. Contraception

Mirena is an effective contraceptive for 5 years. It is a very acceptable and immediately reversible contraceptive, with a 3 year continuation rates of 75-82%(69).

However, if its effectiveness fails, there is chance of ectopic pregnancy in 1 in 20 women. Overall incidence of ectopic is one in 1000 over a 5 year period.

COMPLICATIONS

a) Expulsion- Partial or Complete . Occurs in 1 in 20 women in 5 years(70)

b) Uterine perforation

c) Ovarian cysts- Surgical treatment is rarely needed. 94% resolves spontaneously, in 6 months(71).

d) Risk of pelvic inflammatory disease is low, less that 1 per 100 women. Risk is high only in the first 20 days after insertion.

COSTS

The American data suggests that IUS is the most cost effective therapy for Abnormal Uterine Bleeding(72).

OTHER FORMS OF MEDICAL MANAGEMENT

Cyclical Hormonal Regimens- This is prescribed by 11% of general practitioners. Overall reduction in mean blood loss was form 158 ml to 75 ml. The fear of thromboembolic disease in older women makes it unpopular. The third generation OCPs have increased risk of venous thromboembolism. OCPs act by making the endometrium inactive, reducing the endometrial prostaglandin synthesis and altering uterine fibrinolysis. The common side effects are, headache, migraine, nausea, acne, weight gain, breast discomfort, hypertension, thrombosis, stroke and jaundice.

Prostaglandins – NSAIDs reduces blood loss by inhibiting endometrial prostaglandin synthesis. The reduction ranges from 22% to 46%. It is usually prescribed with oral contraceptives. The additional benefit is that NSAIDs reduces dysmenorrheal and headaches during menstruation. The side effects include nausea, vomiting, gastric discomfort, diarrhea, headache, bronchospasm, thrombocytopenia and hemolytic anaemia.

Antifibrinolytic agents: Tranexamic acid, an inhibitor of fibrinolysis, and has showed a mean reduction in blood loss from 295 ml to 155 ml. The reduction in blood loss was 44% with tranexamic acid. The beneficial effect lasts only during the treatment cycle. The side effects include, nausea, vomiting, diarrhea, dizziness, visual disturbances, cerebral thrombosis.

Androgens:

Danazol is a synthetic androgen with anti-oestrogenic and antiprogestogenic activity. It acts by inhibiting pituitary gonadotrophins and by local endometrial effects. The endometrium becomes thinned out, and the menstruation decreases, leading to amenorrhoea in large doses, whereas small doses causes only decrease in bleeding during menstruation. Overall there was a reduction of MBL of 60%, when compared to NSAIDs with a 20% reduction in blood loss.

Androgenic side effects are weight gain, muscle cramp , skin rashes, voice change, bloating and reduction in breast size.

GnRH agonists: Causes hypo-oestrogenic state and endometrial atrophy. MBL reduced from 131 ml to 11 ml after 3 treatment cycles., 80% of patients being satisfied. Side effects include menopause like symptoms and vaginal dryness. Long term treatments carry risks of osteoporosis.

Patients who are suffering from abnormal uterine bleeding also usually have anaemia, and hence all patients, should be prescribed, oral iron, folic acid, protein and vitamin supplementation.

First generation endometrial ablation includes: roller-ball endometrial ablation, loop endometrial resection and Laser endometrial ablation.

This is performed early in the proliferative phase of menstruation, when the endometrial linning is thin. A sharp or suction curettage is done immediately before ablation. Pretreatment with GnRH, danazol, progesterones, or combined oral contraceptive pills, makes the endometrium thin, and has the advantage of good hysteroscopic view.

Endometrial laser ablation- Normal saline is used as the distending fluid of choice. There are two techniques; The dragging technique and the blanching technique. It is important that the tip of the laser fibre is in view and it should move rapidly, to avoid excessive coagulation and thermal necrosis. The disadvantages are that it is expensive, slowest of all techniques, greater risk of fluid overload and need for safety guidelines.

Roller ball endometrial ablation- The energy used for this is electrosurgical. It is available in 2.5 mm and 5 mm diameter and electrocoagulation is the principle behind the procedure. It is easy to perform, has shorter operating time, less risk of perforation and haemorrhage. The most important disadvantage is , that there is no sample for endometrial histology.

Loop endometrial resection- Transcervical resection of the endometrium is an effective method of treating patients with dysfunctional uterine bleeding. It can be combined with hysteroscopic myomectomy in case of menorrhagia with submucous fibroids. It provides tissue for histology, suitable for a thick endometrium; it however requires skill and the disadvantage is that it has a greater risk of uterine perforation.

Second generation endometrial ablation includes :

a) **Cryotherapy**- This is a non hysterscopic technique which uses cold temperatures for the purpose of destruction of the endometrium. The cryoprobe is cooled to -90.C, using liquid nitrogen or a gas mixture to create ice balls.

b) **Thermal ballon ablation** – Endometrial destruction is by conducted heat. It is quick to perform and has significant reduction in the menstrual loss.

c) **Microwave endometrial ablation**- the local heating effect causes coagulation and the depth of the endometrium should be more than or equal to 10 mm. Pain scores and bleeding significantly reduced.

d) **Electrode:mesh – NovaSure**- This consists of a disposable hand piece and a computerized generator. The amenorrhea rate is around 65%.

e) **Hydrothermablation**- In this procedure, heated saline circulates freely within the cavity, introduced through the hysteroscope. The patients were discharged after 2 hours of the procedure.

f) **Laser interstitial hyperthermy**- This is a blind procedure, where the temperature within the uterine cavity reaches 102.C.

g) **Photodynamic therapy**- Topical photosensitizing agent is taken by the endometrium, reach upto the basalis layer. Further studies required.

Hysterectomy-

It is 100% successful in treating abnormal uterine bleeding, and the satisfaction rates after hysterectomy are very high. Abdominal compared to laparoscopic surgery demonstrated no difference in the quality of life. Whenever possible, vaginal hysterectomy should be performed.

METHODOLOGY

This study was approved by the Research Committee and Institutional Review Board (Ethics Committee) of Christian Medical College, Vellore. The study was reviewed in detail by the research committee and was accepted for follow up of patients for whom Mirena, was inserted between 2007 to 2011.

Sample size

Studies have proved that the menstrual blood loss, is reduced by 95% by 6 months and 97% at the end of one year, after insertion of Mirena. Hence the sample size was calculated, with a precision of 3%, and desired confidence level of 95%, as 124.

Confidence Interval(%)	Sample size(n)
90	87
95	124
99	215

Recruitment

The records on insertion of Mirena, were obtained from the procedure room, in the Out patient Department , Obstetrics and Gynaecology, and the hospital numbers of the patients , who had insertion of Mirena, from the year 2007 to 2011 were collected.

a. **Participants:**

INCLUSION CRITERIA

1. Married women
2. Age group (18-50 yrs)
3. With Mirena inserted for Menorrhagia , Endometriosis, Adenomyosis , Firboid and Endometrial hyperplasia.

EXCLUSION CRITERIA

1. Age above 50 yrs
2. With history of malignancy
3. Where Mirena was inserted for Contraception alone.

Those patients who had a contact number were contacted over phone and enquired about insertion of Mirena, the symptoms they presented with, reason for insertion, number of days of bleeding, whether excessive, and whether associated with pain. The survival analysis was done and patient asked whether Mirena was insitu , removed or expelled.

Those patients who had inserted Mirena, and continued to use for one year and above, and were willing to be followed up, were sent by registered post, questionnaires translated to hindi, and the patients allowed to fill the questionnaire, after a written consent.

Those patients who had inserted Mirena, and continued to use for one year and above, and were willing for a telephonic interview, were explained about the study and an oral consent obtained, for follow up.

The general proforma (Annexure II), which includes general information about the patient, including the indication, bleeding pattern, associated symptoms, haemoglobin before and after one year of insertion, associated comorbidities, whether ultrasound and endometrial biopsy were done, were analysed.

Menorrhagia was assessed by using the **Uterine Fibroid Symptom and Health-Related Quality of Life Questionnaire (UFS-QOL)** (Annexure III) , which includes a set of 37 questions. This proforma contains questions which assesses the following:

a) Symptom severity (8 questions)

b) Concern (5 questions)

c) Activities (7 questions)

d) Energy/Mood (7 questions)

e) Control (5 questions)

f) Self Consciousness (3 questions)

g) Sexual function (2 questions)

UFS-QOL proforma before and after one year of insertion were filled separately, and the health related quality of life compared. Scoring ranged from 1 to 5; a score of 5 was given to the most distressing symptom, and the total score calculated.

SF-36 questionnaire (Annexure IV)

The SF-36 questionnaire contains a set of 36 questions. The questionnaire was used to assess the quality of life in all patients inserted with Mirena, unlike UFS-QOL, which was used in patients only with menorrhagia. The SF-36 questionnaire was used to assess the following:

a) Physical functioning

b) Role limitations due to physical health

c) Role limitations due to emotional problems

d) Energy/ Fatigue

e) Emotional well being

f) Social functioning

g) Pain

h) General health

The positive answers were given a maximum score of '100', and the most negative answer a score of '0'.

Visual analogue scale (VAS) (Annexure V)

The improvement in pain for Endometriosis, was assessed by the Visual analogue scale (VAS) , which was used for Pain analysis, in all patients complaining of pain.

Scores of pain before insertion of Mirena and one year afte Mirena, were obtained. Both these percentages were compared and the improvement calculated, and significance derived at.

Clininical global impressions scale (CGI SCALE – GLOBAL IMPROVEMENT ITEM) (Annexure VI)

The degree of satisfaction was followed up using the CGI Scale. The maximum level of satisfaction was scored 7 and who were very much dissatisfied, were scored 1.

Statisical Analysis of data:

Paired t test was used for continuous variables with a 95% confidence interval and significance were calculated .

Survival analysis was also done and the reason for removal was compared by Tarone-Ware method.

RESULTS

The total number of patients who had insertion of Mirena from 2007 to 2011 were 353 patients, out of which only 177 patients were followed up.

Baseline characteristics of patients followed up after insertion of Mirena.

The age of the patients who had insertion of Mirena were between 25 to 50 years of age, the mean age being 38.57 yrs.

The mean BMI of patients who had insertion of Mirena was 25.96.

Table 11 : Baseline characteristics

Variables	Mean±SD n%
Age(years)	38.5 ± 5.7
Height(cms)	154.7± 5.7
Weight(kg)	62.2± 11.7
BMI kg/m2	25.96± 4.5

Table 12: Year of Insertion of Mirena

Year of insertion	Number of patients inserted Mirena	Number of patients followed up
2007	23	8
2008	32	19
2009	67	20
2010	123	64
2011	108	66
Total	353	177

Parity in 49% of patients who had insertion of Mirena was 2.

Number of women who had 2 children were 51%.

Table 13**: Number of living children for people with mirena insertion.**

No. of children	n	%
O	8	4.6
1	51	29.1
2	90	51.4
3	18	10.3
4	5	2.9
5	3	1.7

Figure 8 : **Place distribution**

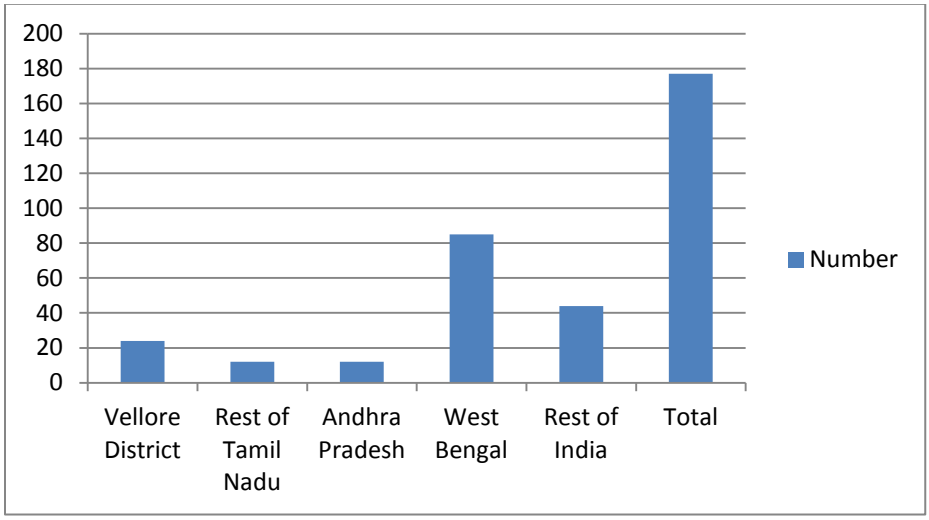


Table 14: The number of patients who completed the study were 110.

Completed study	110
Expelled	36
Removed	19
Improved but not contactable	09
Died	03
Total	177

Table 15: **Type of Interview conducted for follow up**

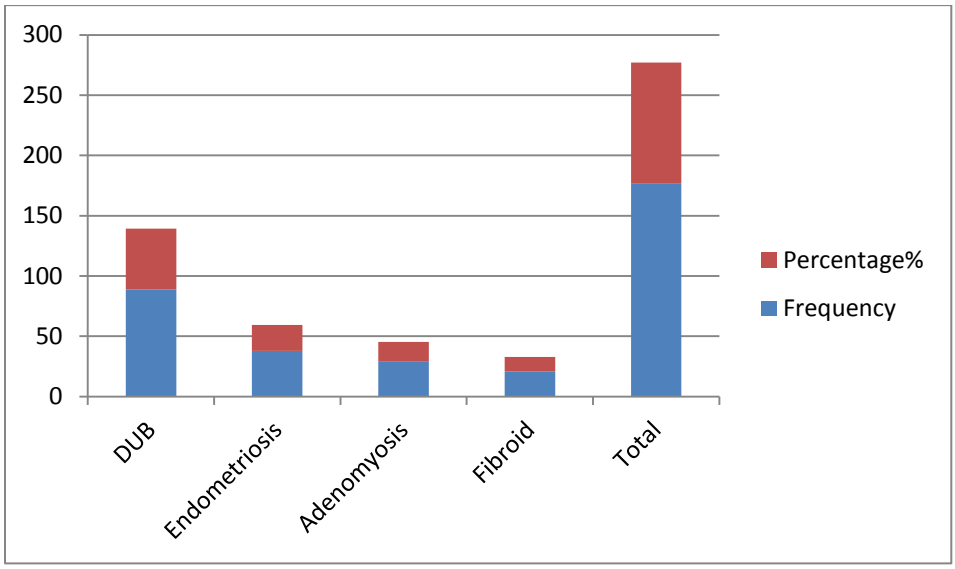
	n	%
Telephonic	117	74.1
Direct	17	10.8
Postal	24	15.2

Dysfunctional uterine bleeding was the reason for insertion in almost 50% of patients.

Table 16: **Reason for insertion of Mirena**

Reason for insertion	n	%
DUB	89	50.3
Endometriosis	38	21.5
Adenomyosis	29	16.4
Fibroid uterus	21	11.9

Figure 9: Reason for insertion of Mirena.



Symptoms prior to insertion of mirena:

88% of patients had menorrhagia, prior to insertion.

Table 17: **Primary symptom before insertion of Mirena**

Indication	n	%
Menorrhagia	142	80.2
Dysmenorrhea	35	19.8

Table 18:**Secondary symptom before insertion of Mirena**

Secondary indication	n	%
Menorrhagia	16	16.8
Dysmenorrhea	75	78.9
Dyspareunia	4	4.2

40.8% of Women who had insertion of Mirena were Sterilised.

Table 19: **Pattern of bleeding before Mirena- Regular**

Regular cycles	n	%
Yes	138	78
No	39	22

89.3% of patients had excessive flow during their menstrual period, and the number of days of bleeding ranged between 1 to 15 days, the average being 7.5 days.

Table 20: **Patients who had dysmenorrhea , before insertion of Mirena**

Dysmenorrhea	n	%
Yes	109	61.9
No	67	38.1

53.1 % of patients had their haemoglobin checked prior to insertion of Mirena; whereas only 13.7% of patients had their haemoglobin checked, after one year of insertion of Mirena.

Table 21: **Haemoglobin before and one year after insertion of Mirena.**

	Mean±SD
Preinsertion Hb(gm%)	10.4±2.4
Hb after 1 year(gm%)	11.5±2.3

27.4% of patients were treated for anaemia; 29.1% received iron supplementation; 23.3% of patients were on treatment for hypothyroidism.

Figure 10: **The comorbidities seen among the patients who had insertion of Mirena.**

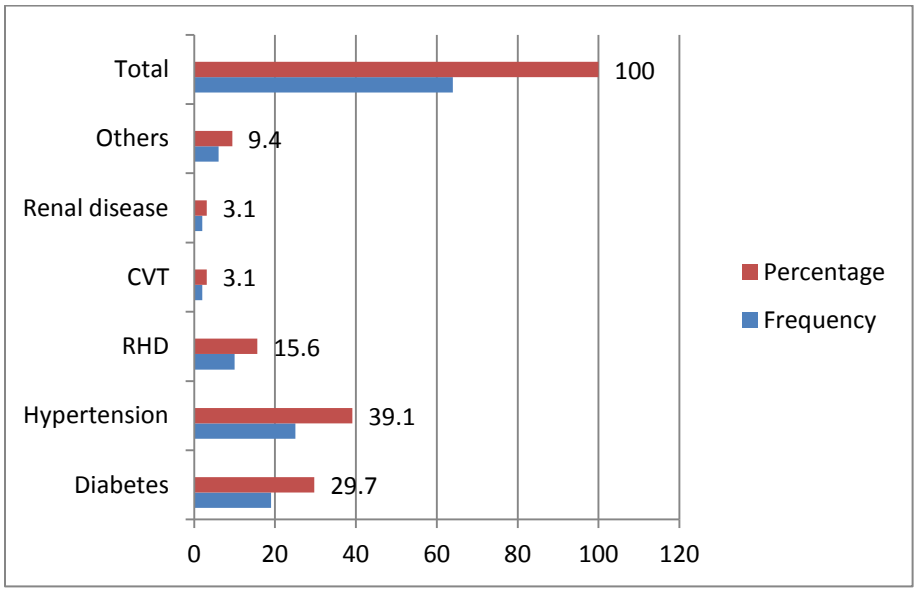
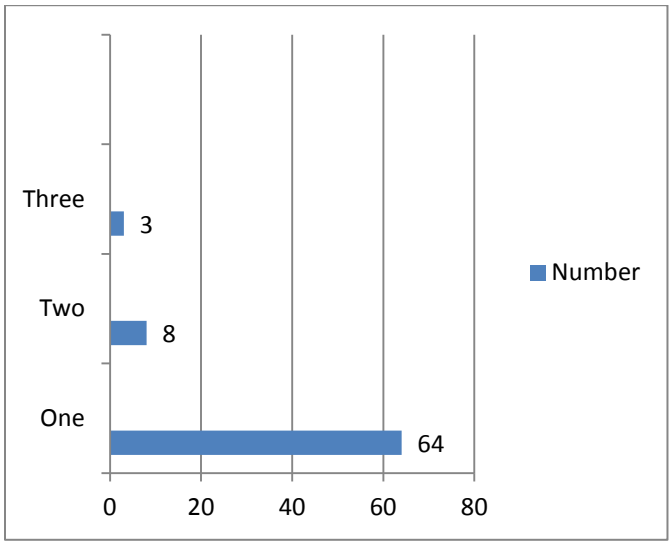


Figure 11: **Number of comorbidities seen among the patient who had insertion of Mirena**



Ultrasound – 75.6% of patients who had insertion of Mirena had a screening ultrasound.

Endometrial biopsy- Only 23.3% of patients had an endometrial biopsy done, for evaluation.

Table 22: **Number of patients with a histopathological diagnosis of Endometrial Hyperplasia**

Endometrial Hyperplasia	n
Yes	3
No	38
Total	41

Figure 12: **Patients with histological diagnosis of endometrial hyperplasia**

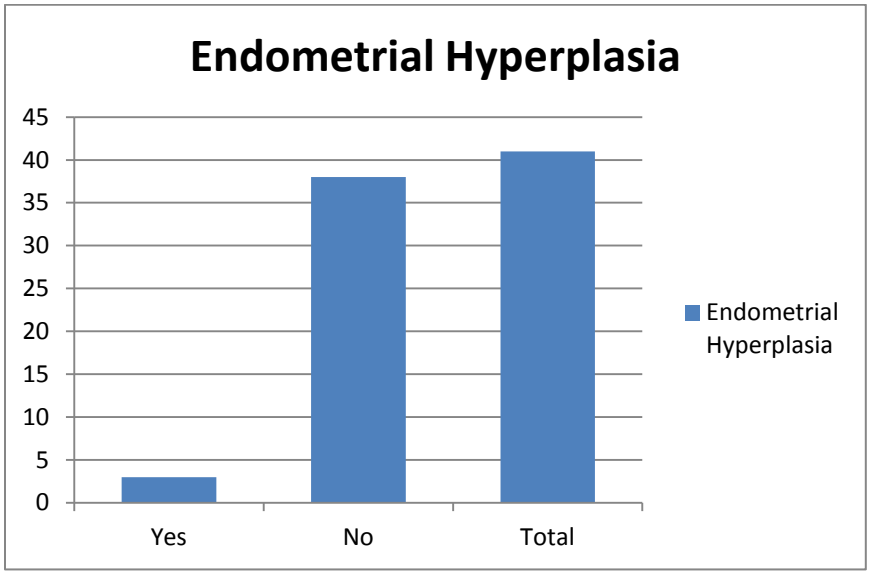


Table 23: **Patients on Mirena who were prescribed additional Medical therapy**

Medical therapy	n	%
Progesterone	33	18.6
NSAIDs/Tranex	25	14.1
OCP	67	37.9
Danazol	03	1.7
None	49	27.7

Figure 13: **Patients who received additional therapy**

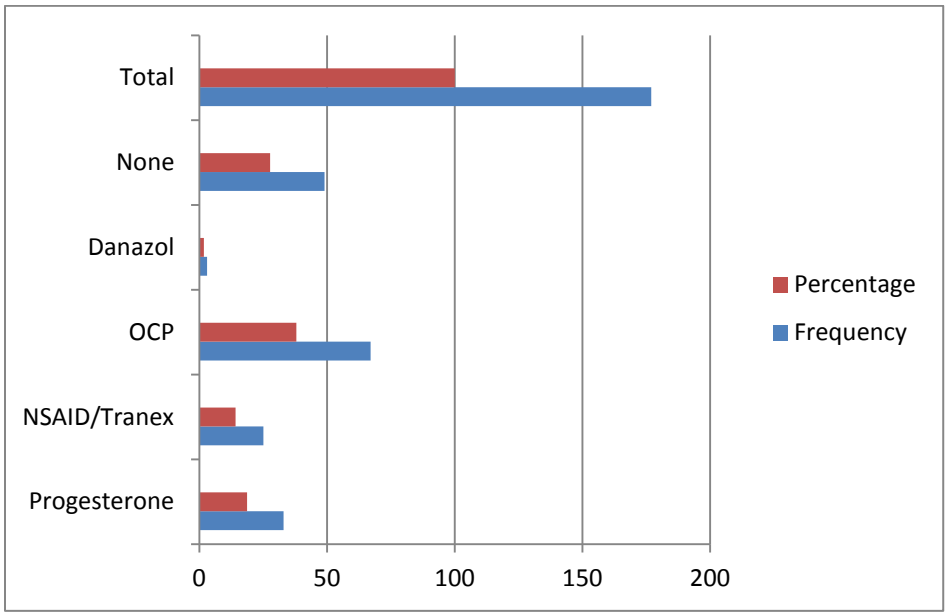


Table 24: **Women who had Improvement of symptoms after one year of insertion of Mirena**

Improvement	n	%
Yes	118	68.6
No	54	31.4

Number of months in which improvement occurred was between 3 to 12 months, the average being 5.36 months.

Table 25**: Pattern of menstruation, after one year of insertion of Mirena**

Pattern of bleeding	n	%
Regular, reduced	28	41.8
Irregular reduced	07	10.4
Amenorrhea	32	47.8

Figure 14: **Pattern of bleeding after Mirena**

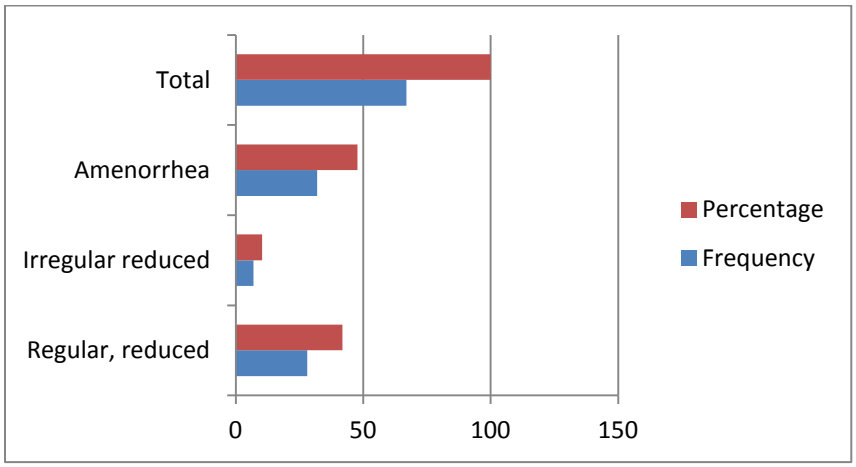


Table 26: **Side effects reported by women after insertion of Mirena**.

Side effects	n	%
Spotting	6	31.6
Weight gain	11	57.9
Breast tenderness	01	5.3
Pelvic pain	01	5.3

Table 27: **Patients who had Voluntary Removal of Mirena**

Voluntary removal	n	%
Yes	25	14.3
No	150	85.7

Figure 15: **Patients who had voluntary removal of Mirena**

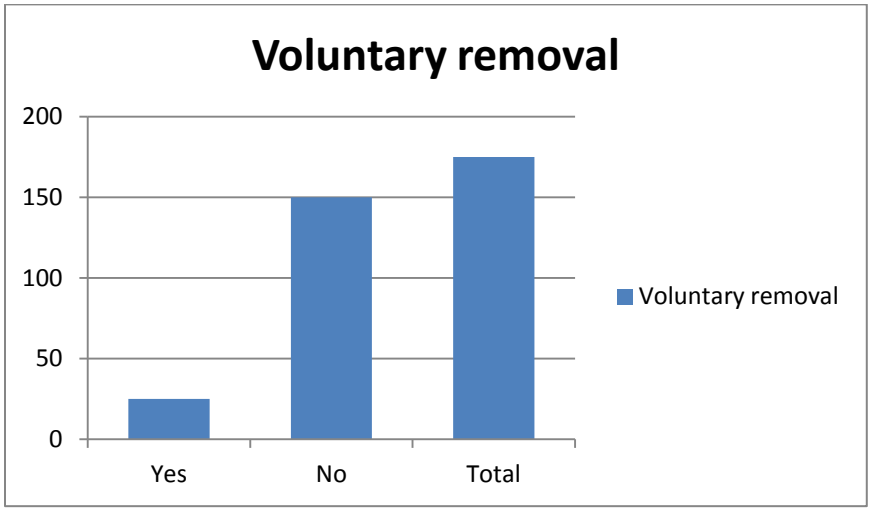


Table 28-. **Number of months within which Mirena was removed and expelled**

No. of months	Mean±SD
Removal	16.68±14.88
Expulsion	6.55±7.39

Of all the patients who voluntarily removed Mirena, 76% of the patients removed within one year of insertion.

Figure **-16: Reason for removal of Mirena**

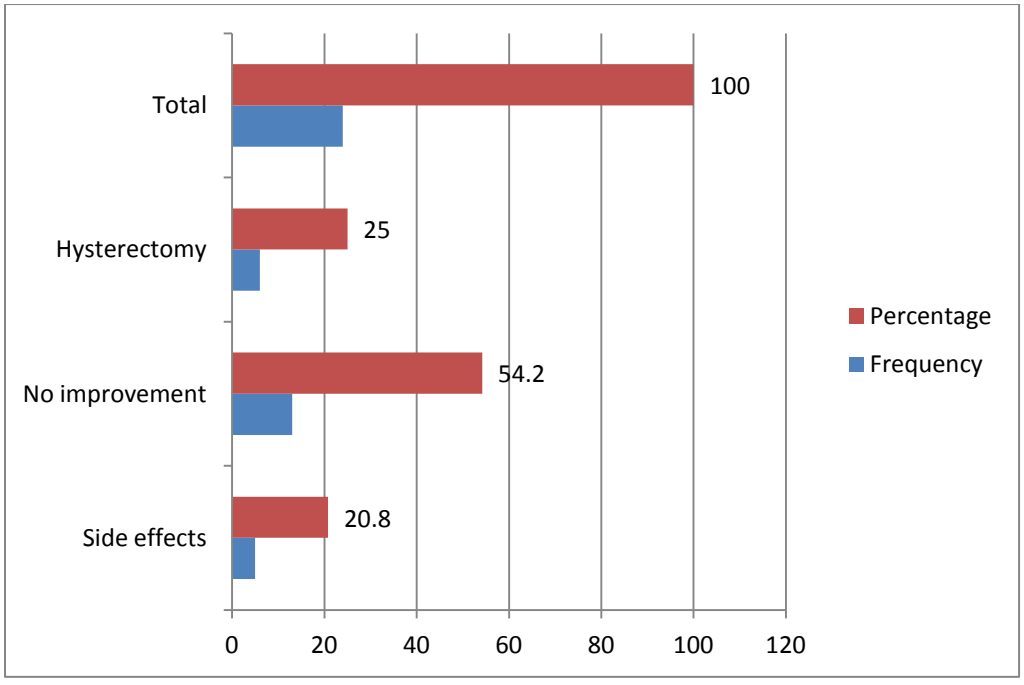


Table 29: **Number of women who spontaneously expelled Mirena**

Expulsion	n	%
Yes	41	23.4
No	134	76.6

Table 30: **Number of Women who had reinsertion of Mirena after expulsion or removal**

Reinserted	n	%
Yes	04	6.3
No	59	93.7

Table 31: **If Mirena was not reinserted what was the treatment taken**

Treatment	n	%
Medical management	33	55
Hysterectomy	27	45

Table 32 : **CGI SCALE FOR SATISFACTION AFTER MIRENA**

Satisfaction	n	%
Very much dissatisfied	1	0.9
Much dissatisfied	4	3.7
Neither satis/ Nor dissatisfied	1	0.9
Minimally satisfied	12	11.2
Much satisfied	16	15.0
Very much satisfied	73	68.2

Table 33: **Final inference on satisfaction**

Satisfaction	n	%
Satisfied	91	83.5
Minimally satisfied	12	11.0
Undecided/worse	06	5.5

Table 34: **VISUAL ANALOGUE SCALE FOR PAIN ANALYSIS:**

Comparing pain before insertion of Mirena with one year after insertion of Mirena, the mean pain reduced from 86.62% to 14.22%.

VAS	Mean
Before insertion of Mirena	86.62%±20.31
One year after insertion of Mirena	14.22%±20.10

Table 35: **Visual analogue scale – Paired ‘ t’ test**

VAS	Mean± SD	Mean Change	95% CI	P value
Before	86.2±20.3	72.40	66.10 to 78.70	<0.01
After	14.2±20.1			

Table 36: **UFS –QoL Symptom severity (Menstrual symptoms), before Mirena and one year after Mirena, shows a significant reduction of symptoms.**

Symptom severity	Mean ±SD	Mean change	95% CI	P value
Before	25.43 ± 4.55	13.87	12.67 to 15.06	< 0.01
One year After	11.56 ± 5.65			

Table 37: UFS – HRQL(Uterine fibroid symptoms, health related quality of life)

UFS-HRQL	Mean ±SD	Mean change	95% CI	P value
Concern	17.53 ± 4.49			
Before	6.44 ± 3.30	11.09	10.01 to 12.76	< 0.01
After				
Activity				
Before	25.98 ± 4.75	16.18	14.68 to 17.67	< 0.01
After	9.80 ± 5.36			
Energy/Mood				
Before	26.42 ± 4.77	15.70	14.11 to 17.28	< 0.01
After	10.72 ± 6.56			
Control				
Before	19.26 ± 3.76	11.78	10.51 to 13.04	< 0.01
After	7.48 ± 4.78			
Self conscious				
Before	7.67 ± 2.50	2.52	1.98 to 3.05	< 0.01
After	5.15 ± 2.30			
Sexual function				
Before	7.01 ± 2.29	3.49	2.92 to 4.06	< 0.01
After	3.51 ± 1.97			
HRQL				
Before	1.03 ± 16.70	6.079	55.17 to 66.28	< 0.01
After	43.07±20.92			

Table 38 **: UFS –QoL analysis in toto including analysis of menstrual severity and health related quality of life**

UFS total	**Mean ± SD**	**Mean change**	**95% CI**	**P value**
Before Mirena	**129.23 ± 19.00**			
One year after Mirena	**54.63 ± 25.86**	**74.60**	**68.11 to 81.08**	**< 0.01**

Table 39: **Haemoglobin values before and after one year of insertion of Mirena**

	Mean ± SD	Mean Change	95% CI	P value
Before Mirena	9.80 ± 2.39	-1.55	-3.09 to -0.03	0.049
One year after Mirena	11.35 ± 2.59			

Table 40: **SF 36- Scoring of quality of life after one year after insertion of Mirena.**

SF 36 – Scoring (Percentage)	Mean ± SD	Median (IQR)
Physical	88.5 ± 17.86	100 (80,100)
Role- Physical health	86.57 ± 28.68	100 (100,100)
Role- Emotional	86.72 ± 30.20	100 (100,100)
Energy	73.98 ± 20.29	80 (65,90)
Emotional	77.07 ± 19.42	84 (72,92)
Social	89.0 ± 21.32	100 (87.5,100)
Pain	83.63 ± 25.59	95 (77.5,100)
General health	78.10 ± 23.16	90 (70,95)

Table 41: **Overall survival time (Time of discontinuation of Mirena)**

Median (Months)	95% CI
6.00	4.0 to 7.9

The median duration of Mirena removal was 6 months (4 to 7.9).

Figure 17: **Survival Analysis**

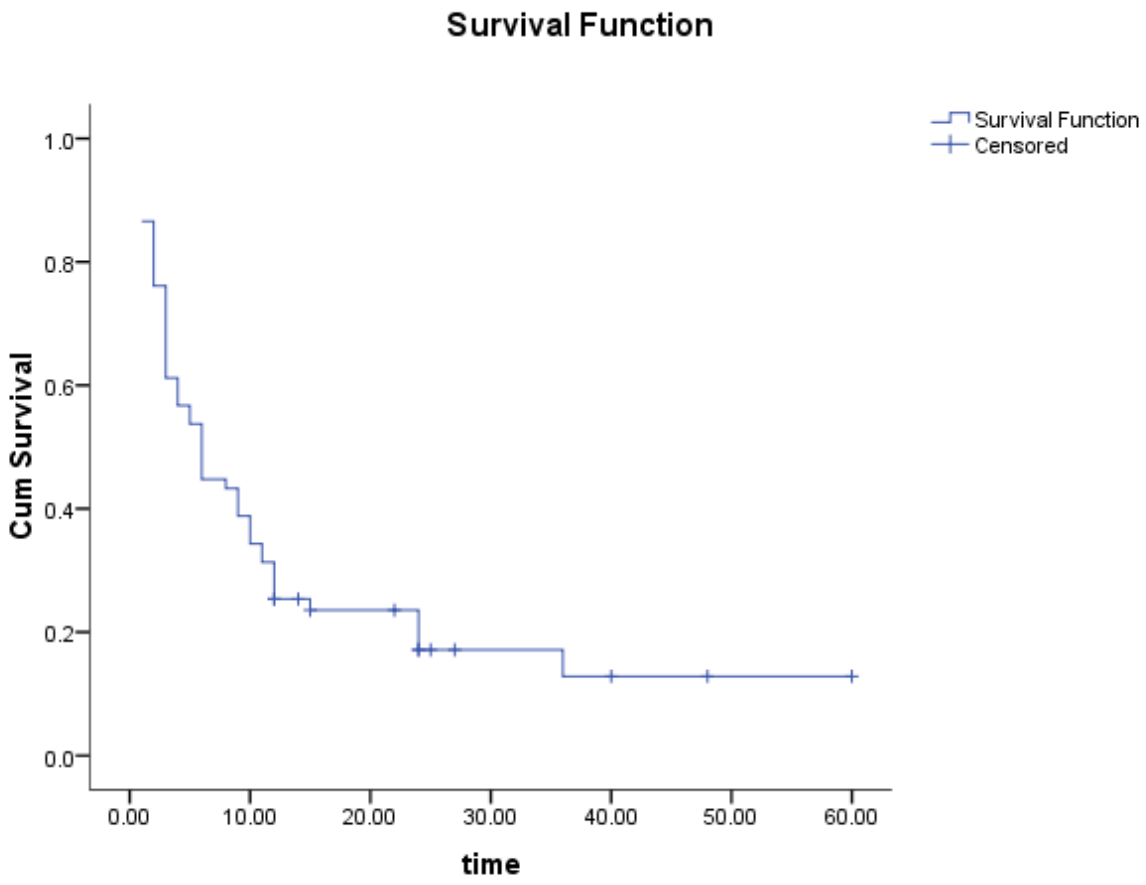
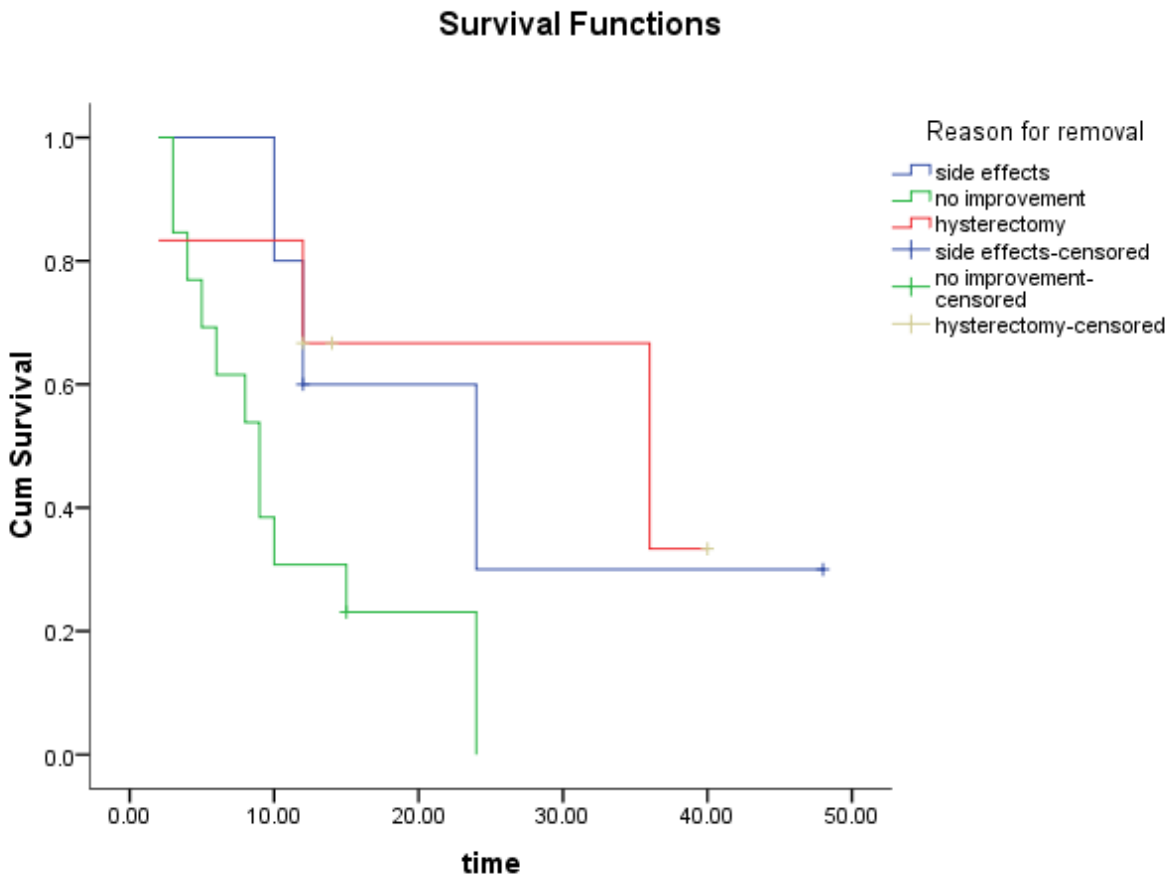


Table 42: **Reason for Voluntary Removal of Mirena**

Reason for Removal	Median (Months)	95% CI	P value
Side effects	24.0	5.28 to 42.71	
No improvement	9.0	5.56 to 12.43	0.059
Hysterectomy	36	0.073	

The reason for Mirena Removal were Side effects, No improvement and Hysterectomy and the duration were 24, 9 and 6 months respectively; yet the difference is not found to be statistically significant.

Figure 18 : **Survival Functions (Reason for removal)**



DISCUSSION

The term abnormal uterine bleeding is used for both ovulatory and anovulatory bleeding. Abnormal uterine bleeding affects 10 – 30% of women of the reproductive age group, and about 50% of women in the perimenopausal age group.

The average length of the cycle is 28 days, the average duration is 4 days and the average blood loss during menstrual cycle is between 30 to 40 ml per cycle. The 90^{th} percentile for blood loss during menstruation was 80 ml, and anaemia was significantly increased in women with a loss of greater than 60 ml. Loss of more than 80 ml per menstrual episode is defined as menorrhagia.

However 20% of women who have documented normal flow, complained of menorrhagia, and seeked treatment(2).

The physician may not be able to assess the volume of blood lost during menstrual cycle from the history. The different methods by which the menstrual blood loss can be assessed are as follows:

Subjective assessment-

Direct measurement of the menstrual blood loss is the only reliable way to diagnose menorrhagia. The other way of assessment is by the rate of change of sanitary pads during the flow and the total number of pads and tampons used (75).

It is an inaccurate method and there was no correlation between self assessment, number of sanitary pads used, duration of the menstrual period and the objective menstrual

blood loss (7). Only 44% of women complaining of menorrhagia, had a menstrual blood loss of more than 80 ml.

Objective measurement-

The exact amount of haemoglobin lost is measured by the alkaline hematin method. The modifications of the alkaline hematin method for the diagnosis of heavy menstrual blood loss improves the recovery rate from 89% to 98%, and so it can used as a reliable method(74). Menstrual blood is extracted by soaking the sanitary pads in 5% sodium hydroxide and haemoglobin converted to alkaline hematin; it is centrifuged and the optical density measured by spectrophotometry, and compared with the patient's venous blood. But this test is laborious, costly and causes inconvenience to the patient, though it is accurate.

When there was a fall in haemoglobin, with increase in menstrual blood loss, a rise in the ferritin levels were noticed, but was relevant only if the menstrual blood loss was more than 120 ml/cycle(76).

Indirect (semi-objective) measurement –

Clinical features associated strongly with excessive blood loss are frequency of changing sanitary pads, passage and the size of clots and flooding. Low ferritin level picks up 60% of women, with loss more than 80 ml(77).

The menstrual pictogram provides a simple way of measuring the blood loss. Pictorial blood assessment charts may not accurately reflect the hygiene products used (73). Evaluation of this chart by further studies, debated its validity.

The NICE guidelines (National Institute for Health and Clinical Excellence), does not routinely recommend assessment of blood loss in menorrhagia(78).

The ACOG does not recommend blood count or testing for thyroid hormones for women with excessive bleeding(79). Evidence based guidelines from the Royal College of Obstetricians and Gynaecologists, recommend," these tests, and thyoid and bleeding disorder evaluation should be done if there are clinical or historical features"(80).

Menorrhagia can result in severe anaemia. 58% reported a history of anaemia, and 89% of them received oral iron therapy(81).

Treatment of menorrhagia results in substantial improvement in the quality of life.

Medical therapy available for menorrhagia are Non steroidal anti inflammatory drugs, antifibrinolytic drugs, progestogens, oral contraceptives and danazol. All these therapies are partially effective in reducing the menstrual blood loss. The choice of medical treatment is the choice of the individual. Local LNG-IUS ranks much higher than all other medical treatments, when the effectiveness, side effect and acceptability are taken into account.

The other forms of treatment include endometrial resection/ablation and hysterectomy. Hysterectomy is a definitive treatment , but the risk of surgical morbidity and the cost involved should be considered.

Studies comparing the long term efficacy of LNG-IUS and Endometrial resection ,show that in both the treatments there was a reduction in the menstrual bleeding.

The NICE in the UK, has recommended that Mirena, should be considered as the first line of treatment, if no structural abnormalities are detected. Mirena proved superior to oral treatment in achieving normalization of blood loss and also in frequency of side effects.

The reduction in menstrual blood loss was almost 94% in 3 cycles and the continuation rate was 76%.

At the end of 6 months of use of Mirena, 64.3% of patients cancelled their surgery.

In a follow up study for 5 years, 42% of patients ultimately had hysterectomy. Expulsion was low occurring in 1 in 20 insertions.

The results derived from this study on follow up of patients inserted Mirena, from 2007 to 2011 are:

There were a total of 353 insertions, out of which only about 50% of patients, could be followed up.

The incorrect address, missing phone number were the main drawbacks. This could have been avoided if the same study, could have been done as a prospective study.

Comparing the place distribution, it was analysed that, three fourth of the patients were from north India, and almost 50% of the patients of the total number were from the West Bengal. Though the questionnaires were translated into hindi, there was practical

problems in the patients understanding the questions, as the questionnaires were elaborate. Therefore almost 74% of the patients were conducted telephonic interviews.

62% of the patients had Mirena in situ for one or more years. While the expulsion rate was 20% , the reason probably was that additional medical therapy was not prescribed and the flooding probably would have continued leading to expulsion of Mirena.

The rate of voluntary removal was about 10.7%, and most of the removal were within the first 6 months of insertion. This is probably because, the patients did not wait long enough, for the onset of its effect. If waited enough with additional medical therapy, to control acute symptoms, they would have improved, and this could have avoided the removal of Mirena.

Three patients who had insertion of Mirena for menorrhagia died, due to severe comorbidies . (acute myeloid leukemia, valvular heart disease requiring anticoagulation and chronic renal failure).

Dysfunctional uterine bleeding was the most common diagnosis made prior to insertion of Mirena. 50% of patients were inserted Mirena for Dysfunctional uterine bleeding and 21% for endometriosis. The other reasons include adenomyosis and uterine fibroids, causing symptoms.

Menorrhagia was the primary symptom in 80% of patients and dysmenorrhea was the secondary symptom in 78% of patients. Only 4.2% of patients, had complained of dyspareunia.

a) Among the baseline demographics, the mean age of the patients was 38.5 years, the average BMI was 25.9 kg/m2, the average parity was 2; 40.8% of women were sterilized

b) 78% of patients had regular excessive flow, the average number of days of bleeding was 7.5 days, 62% had associated dysmenorrhea.

c) Haemoglobin prior to insertion was done in 53% of patients with a mean value of 10.4 gm%; Though the minimum haemoglobin level was 3 gm%, there was one patient with a haemoglobin of 17 gm% pre insertion. Only 27% of women were treated for anaemia, whereas iron supplementation was given to 29% of the patients.

d) 23% of women had hypothyroidism, 30% had diabetes, 39% had hypertension. 15% of patients with Rheumatic heart disease, some on anticoagulation had response with Mirena.

e) 75% of the patients had an ultrasound done; 23% of them had endometrial biopsy done, of which endometrial hyperplasia, was reported only in 3 patients.

f) 38% of patients were prescribed oral contraceptive pill and 18.6% were prescribed oral progesterones, in addition to Mirena in the first 3-6 months, as additional therapy.

g) Haemoglobin was done only in 13.7% of patients, one year after insertion; hence the preinsertion haemoglobin, could not be compared with the post insertion haemoglobin, of the same patient. If this could have been done as a prospective study, a quantitative analysis could have been analysed and significance proved.

h) 68.6% of patients had improved with Mirena symptomatically, and the mean duration was 5.3 months, in which improvement was noticed. The Amenorrhea rate was 47.8%

and almost 41.8% had regular but reduced bleeding. The commonest side effect was weight gain, followed by spotting.

i) 76% of those who removed Mirena voluntarily, removed it in less than one year; Mean duration of removal of Mirena was 16.6 months ; around 54% of the removal was because, there was no improvement; and mean duration of expulsion was 6.5 months; only 6.3% of women who expelled had reinsertion of Mirena; while 45% of them who expelled had hysterectomy.

j) The visual analogue score – The average pain before insertion was 86.6% which had reduced to 14.2% one year after insertion, with a 95% confidence interval of 66 to 78 and p value was significant(<0.01).

k) 68% of the patients were very much satisfied; and almost 83.5% of women were satisfied(very much satisfied and much satisfied);

1) Comparing the UFS-QoL, before and after one year of Mirena, there was a significant improvement in the symptom severity, concern, activity, energy, control, self consciousness, sexual function, after one year of insertion of Mirena. The qualitative analysis done before insertion and one year after insertion of Mirena, in those with menorrhagia, by the UFS-QoL questionnaire, showed that , the Symptom severity scoring by UFS-QoL, before and after insertion of Mirena , had an improvement, that was statistically significant. Similarly the health related quality of life analysed by UFS-QoL , before and after one year after insertion also improved significantly, and was statistically significant.

l) The SF 36 scoring showed high scores proving that the quality of life was good, one year after insertion , but it could not be compared with SF before Mirena, for significance, as it was not done. The various aspects that are analysed are physical functioning, role of physical health, role of emotional problems, energy, emotional well being, social functioning and pain.

m) There was no significant improvement in the haemoglobin values before and after, because of the less numbers.

n) Survival analysis- Overall duration of discontinuation of Mirena was 6 months (4 to 7.9 months). The various reasons for removal were side effects, absence of improvement and hysterectomy, but the difference is not statiscally significant.

LIMITATIONS

1) Anderson JK et al ,Br J Obstet Gynaecol 1990; 97: 690-4, states that the menstrual blood loss is reduced by 95% by 6 months and 97% at the end of 1 year. Therefore a sample size of 124 was chosen. However as this is an observational study on the patients who had Mirena in the past, the record of the contact number were not complete, and even if complete, were wrong numbers and wrong addresses. If done as a prospective analysis, it will be possible to have complete electronic records.
2) All women did not have their haemoglobin checked, before and one year after insertion, and hence not comparable, causing inability to prove the significance.
3) The questionnaires were elaborate causing inconvenience in postal interviews, though they were all translated in the regional language(hindi).

CONCLUSIONS

1 The total number of patient who had insertion of Mirena , from 2007 to 2011, in Christian Medical College and Hospital were 353.

2 Though there was an improvement from mean preinsertion haemoglobin of 10.4 gm% to post insertion haemoglobin of 11.5 gm%, this improvement was not statistically significant . Hence the quantitative improvement could not be proved, statistically.

3 The qualitative analysis done before insertion and one year after insertion of Mirena, in those with menorrhagia, by the UFS-QoL questionnaire, showed that :

   a) The Symptom severity scoring by UFS-QoL, before and after insertion of Mirena , had an improvement, that was statistically significant.

   b) The health related quality of life analysed by UFS-QoL , before and after one year after insertion also improved significantly, and was statistically significant.

4 The effectiveness of Mirena in those with dysmenorrhea , before and after insertion of Mirena, analysed by the Visual analogue scale(VAS), showed that the mean change was 72.4%, and paired ‘t’ test, showed that the improvement was statistically significant.

5 The health related quality of life, analysed by the SF 36, at one year after insertion of Mirena, showed that the mean score was ‘High’, which defines a more favourable health state.

6 The level of satisfaction among those using Mirena, showed that 83.5% of patients were satisfied, out of which 68.2% of patients were very much satisfied.

7 Survival analysis showed that the median duration of Mirena removal was 6 months. If the patients had waited, with additional medical therapy, removal could have been avoided, and they would have improved, at the end of one year. Around 23.4% of patients had expulsion of Mirena.

Sl no	hospital	no	Age	bmi	Interview	Reason	symptom	Cycles	Bleeding da	Dysmen	pre Hb	PostHb	USG	biopsy	Med Rx	improveme
1	59719	D	47	24.46	1	1	1	1	15	1	-	-	2	1	1	3
2	204445	B	39	23.78	2	1	1	1	8	2	8.3	11.8	2	2	-	3
3	690059	B		25.10	2	2	1	1	6	1	11.6	-	1	2	3	6
4	37376	D	45	29.97	1	4	1	1	8	1	10.7	-	1	1	2	12
5	691002	D	30	23.42	1	2	1	2	15	1	11.5	-	1	2	4	3
6	53676	B	36	22.19	1	1	1	2	7	1	11.0	-	1	2	2	12
7	917899	D	42	-	1	1	1	2	8	2	-	-	1	2	-	3
8	478014	D	46	-	1	1	1	1	5	2	10.6	12.1	1	2	3	6
9	351275	D	49	19.56	2	2	1	2	5	2	-	-	1	2	-	6
10	529767	B	43	-	2	4	1	1	5	2	8.4	13.2	1	2	1	3
11	939225	D	41	33.32	1	1	1	1	5	1	-	10.5	1	1	2	3
12	36330	D	38	-	3	1	1	2	7	1	-	-	2	1	3	6
13	743481	D	34	16.89	3	2	2	1	51	1	10.7	-	1	2	3	6
14	188576	A	49	24.88	2	1	1	1	10	1	12.4	-	1	2	3	3
15	624377	B	37	27.53	1	1	1	2	4	2	11.9	-	1	2	2	31
16	622947	D	25	17.78	1	1	1	1	8	1	6.2	-	2	1	-	6
17	989608	C	48	23.81	1	1	1	1	7	1	10.8	12.4	2	2	3	3
18	81515	F	35	26.91	1	1	1	1	6	1	-	-	2	2	3	3
19	841650	A	49	26.14	3	1	1	1	8	2	11.4	12.1	1	1	1	12
20	840762	D	47	32.04	2	1	1	1	5	2	13.2	-	1	1	1	6
21	620445	D	50	38.57	2	1	1	2	7	1	17.0	-	1	1	-	3
22	126233	C	32	22.83	2	1	1	1	8	1	8.9	-	1	2	1	3
23	914763	D	39	30.22	2	1	1	1	15	1	-	-	1	2	2	3
24	958998	D	36	19.65	3	3	1	1	12	1	-	13.0	1	2	3	6
25	729730	B	37	-	2	2	1	1	8	1	11.3	-	1	2	3	6
26	356806	D	32	22.31	2	2	1	2	8	2	-	-	1	2	2	6
27	770835	D	35	29.14	1	1	1	2	10	2	-	-	1	2	3	3
28	833526	D	38	24.39	3	2	2	1	3	1	-	-	1	2	3	6
29	446780	D	32	-	1	3	1	1	7	1	-	-	1	2	-	6
30	536981	D	36	-	1	3	1	1	15	1	8.9	-	1	2	3	6
31	761374	D	47	28.13	1	1	1	2	15	1	-	-	2	1	-	12
32	364833	A	43	30.80	2	1	1	1	5	2	-	-	1	2	1	3
33	941364	C	32	18.31	1	1	1	1	7	2	12.1	-	1	2	-	6

Sl no	hospital	no	Age	bmi	Interview	Reason	symptom	Cycles	Bleeding da	Dysmen	pre Hb	PostHb	USG	biopsy	Med Rx	improveme
34	794175	C	32	19.23	1	1	1	1	8	1	-	-	1	2	-	3
35	839468	D	42	27.66	1	4	1	1	8	1	11.7	-	1	1	1	-
36	944025	D	38	26.57	1	1	1	2	15	2	7.5	-	1	2	3	3
37	168468	A	44	27.24	1	1	1	1	10	2	-	-	1	1	-	3
38	990035	B	38	25.15	1	4	1	1	6	1	10.9	-	1	1	3	3
39	623755	D	47	21.88	3	1	1	2	10	2	-	-	2	2	3	6
40	954746	C	34	22.31	1	1	1	2	12	1	-	-	1	2	3	6
41	397081	C	49	24.80	2	1	1	1	15	1	12.4	12.7	1	2	-	6
42	755945	D	26	27.77	2	2	2	2	3	1	-	-	1	2	3	3
43	831195	D	44	24.44	1	1	1	1	3	2	13.5	-	1	2	1	12
44	995812	A	49	26.49	1	1	1	2	10	1	-	14.6	1	2	2	6
45	66769	F	38	22.03	1	1	1	1	9	1	-	-	2	1	2	12
46	656769	D	40	21.64	1	1	1	1	5	1	-	-	1	2	3	3
47	781086	D	39	22.22	1	1	1	1	6	1	-	-	2	2	-	6
48	35603	F	40	32.84	1	1	2	1	7	1	-	-	1	2	2	6
49	682807	D	40	27.11	1	2	1	1	4	1	-	-	2	2	3	3
50	863514	D	48	22.21	3	3	1	2	3	2	-	-	1	2	3	6
51	637566	D	38	26.48	1	2	2	1	5	1	12.2	-	2	2	1	3
52	587109	D	32	30.70	1	2	2	2	12	1	13.5	-	1	2	3	3
53	918735	D	41	34.89	1	1	1	1	5	2	-	-	2	2	-	3
54	848602	D	42	26.67	3	1	1	1	10	2	10.8	-	2	2	-	12
55	459651	D	39	35.65	3	1	1	1	14	1	11.4	-	1	2	-	6
56	870993	D	39	32.47	1	1	1	1	6	2	-	-	2	2	3	3
57	344728	D	33	21.23	1	2	2	1	5	1	-	-	1	2	3	3
58	420430	D	36	20.83	1	1	1	1	8	2	11.9	-	1	2	-	-
59	766602	D	31	26.49	1	2	2	1	5	1	-	-	1	2	3	6
60	670768	D	35	31.47	1	3	2	1	3	1	-	-	1	2	3	3
61	730937	B	35	24.14	1	2	1	1	4	1	-	13.0	1	1	1	3
62	135558	D	38	22.67	3	4	1	1	8	2	12.2	-	1	2	2	6
63	569784	D	39	23.44	3	2	1	1	6	1	-	-	2	2	4	6
64	828652	D	32	26.22	3	3	1	1	15	2	-	-	1	2	3	6
65	840001	D	42	25.78	3	1	1	1	4	2	10.8	-	1	2	3	6
66	769070	D	42	26.40	3	1	1	2	6	2	-	-	1	2	3	6

Sl no	hospital	no	Age	bmi	Interview	Reason	symptom	Cycles	Bleeding da	Dysmen	pre Hb	PostHb	USG	biopsy	Med Rx	improveme
67	741907	D	42	30.63	1	1	1	1	12	1	12.8	-	1	1	3	-
68	934551	D	38	31.23	3	1	1	1	10	1	-	-	2	2	-	6
69	954640	D	27	22.27	1	1	1	1	15	1	13.0	-	1	2	1	3
70	25495	D	49	24.78	1	1	1	2	10	1	9.8	-	1	1	2	6
71	8637	D	34	23.73	1	1	1	1	7	1	10.0	-	1	2	3	3
72	714136	B	32	28.67	1	1	1	2	10	1	13.3	13.1	2	1	-	3
73	796240	D	37	29.43	3	2	2	1	3	1	-	-	1	2	1	6
74	665772	D	40	-	3	1	1	1	15	2	4.7	9.8	1	2	-	12
75	864519	D	30	34.16	1	3	1	1	3	1	-	-	2	2	-	3
76	738965	D	34	23.05	1	2	2	2	8	1	-	-	2	2	2	6
77	666521	D	47	34.25	1	3	1	1	5	1	9.2	10.6	1	2	2	6
78	487177	D	41	25.24	1	2	1	2	8	1	8.9	-	1	1	3	6
79	311794	D	36	32.87	1	1	1	1	8	1	13.3	-	1	2	2	6
80	732671	D	41	28.30	1	2	1	2	6	1	-	-	1	2	3	12
81	81515	F	36	26.64	1	4	1	1	7	1	-	-	2	2	3	3
82	35603	F	39	27.83	1	3	1	1	8	1	-	-	1	2	3	6
83	988938	D	41	26.50	1	3	1	1	8	1	-	-	1	2	3	3
84	211463	D	31	17.44	1	1	1	1	10	2	11.6	-	1	2	-	12
85	803930	C	34	27.63	1	2	1	1	5	1	11.3	11.6	1	2	-	3
86	31984	D	40	24.65	1	1	1	2	7	1	-	-	2	2	3	3
87	44651	C	40	29.24	1	1	1	1	8	2	10.3	-	1	2	2	3
88	827952	D	31	27.27	1	2	2	2	-	2	-	-	2	2	3	6
89	35154	F	32	-	1	3	2	1	3	1	10.8	-	1	2	-	6
90	404731	D	39	25.48	1	3	1	1	8	2	12.0	11.8	2	2	3	3
91	278563	F	40	25.48	1	1	1	1	6	2	7.7	11.5	1	2	-	3
92	338497	D	37	18.51	1	2	2	1	5	1	-	-	1	2	-	3
93	963026	C	45	33.32	1	1	1	1	7	1	-	-	1	1	1	6
94	84807	F	33	17.71	1	3	2	1	6	1	-	11.1	2	2	2	3
95	991637	d	46	23.31	1	2	2	2	6	1	-	-	2	2	-	3
96	601598	D	38	23.92	1	3	2	1	5	1	11.5	-	1	1	3	6
97	519387	C	32	23.19	2	1	1	1	5	1	9.1	13.3	1	2	3	3
98	279512	D	39	34.58	1	1	1	1	5	1	11.4	-	2	2	-	6
99	390710	D	46	22.37	1	4	1	1	9	1	10.4	-	1	2	-	3

Sl no	hospital	no	Age	bmi	Interview	Reason	symptom	Cycles	Bleeding da	Dysmen	pre Hb	PostHb	USG	biopsy	Med Rx	improveme
100	838289	D	38	26.04	1	3	2	1	3	1	11.3	-	1	2	-	6
101	704818	D	-	20.93	1	1	2	1	12	1	10.7	2.0	1	1	1	-
102	905924	D	34	21.93	1	2	2	1	3	1	-	-	1	1	3	6
103	666853	D	29	22.84	3	3	1	1	4	2	12.1	-	1	2	3	6
104	79968	F	43	29.76	3	2	1	2	8	1	12.8	-	1	1	3	3
105	883027	D	32	22.60	3	4	1	1	8	2	-	-	2	2	1	6
106	834520	D	49	-	2	1	1	2	6	1	4.7	9.0	1	1	1	3
107	335132	D	47	29.05	3	4	1	2	5	1	10.7	11.9	1	1	-	3
108	717535	D	25	18.13	1	1	1	1	7	2	11.8	-	1	2	3	12
109	928738	D	44	24.35	3	3	1	1	3	2	-	-	2	2	-	6
110	787835	D	38	29.24	3	2	2	1	3	1	-	-	1	2	3	6
111	793628	D	46	34.70	1	1	1	1	5	-	-	-	-	-	-	-
112	676339	D	46	30.02	1	4	1	2	12	2	13.1	-	1	1	1	-
113	110067	D	35	25.92	1	2	2	1	3	2	-	-	1	2	3	-
114	266584	D	35	28.62	1	2	2	1	3	1	14.1	-	1	2	2	-
115	251235	D	46	27.41	1	1	1	2	13	1	12.0	-	2	2	-	-
116	811545	D	40	22.94	1	1	1	1	8	2	8.4	-	2	2	-	-
117	910350	D	34	16.44	1	2	1	1	5	1	-	-	1	2	3	-
118	919054	D	37	35.20	1	4	1	1	10	2	-	-	1	2	1	-
119	755860	D	40	-	2	1	1	1	14	2	12.2	-	1	1	3	-
120	772148	D	37	34.96	1	1	1	1	5	2	9.2	-	1	1	-	-
121	264743	C	42	22.22	1	4	1	1	12	2	9.9	-	1	1	3	-
122	237741	D	40	24.03	1	1	1	1	5	1	11.2	-	2	2	2	-
123	853665	B	36	-	1	3	1	1	5	1	-	-	2	2	2	-
124	815301	A	47	-	1	1	1	2	5	2	9.5	-	2	2	-	-
125	319183	D	35	29.09	1	3	2	1	5	1	-	-	2	2	3	-
126	878288	D	43	-	1	1	1	1	10	2	12.1	-	2	2	-	-
127	902885	D	32	28.44	1	3	2	1	5	1	9.2	-	1	2	1	-
128	703711	D	38	27.89	1	1	1	2	5	2	10.3	-	1	2	-	-
129	811545	D	42	27.56	1	1	1	1	8	1	5.8	-	1	2	1	-
130	494803	D	30	20.57	1	2	2	1	1	1	-	10.7	1	2	3	-
131	578239	D	44	26.84	1	3	1	2	8	2	6.8	-	1	1	1	-
132	745292	D	40	-	1	4	1	1	7	1	-	-	2	1	-	-

Sl no	hospital	no	Age	bmi	Interview	Reason	symptom	Cycles	Bleeding da	Dysmen	pre Hb	PostHb	USG	biopsy	Med Rx	improveme
133	517373	D	33	23.53	1	1	1	1	7	2	-	-	1	2	2	-
134	580100	D	36	27.24	1	1	1	1	5	2	6.6	-	1	2	2	-
135	435357	D	49	33.23	1	1	1	2	12	2	7.9	-	1	1	2	-
136	525842	D	45	28.33	1	4	1	1	6	1	-	-	1	1	2	12
137	474541	D	35	24.24	-	2	2	1	4	1	-	-	1	2	-	-
138	761694	D	39	27.48	-	2	2	1	3	1	-	-	1	2	3	-
139	195006	D	44	30.67	1	1	1	1	8	2	-	-	1	1	1	-
140	54760	C	33	24.52	-	2	2	1	1	2	-	-	1	2	3	-
141	878073	D	34	19.22	1	3	1	1	10	1	-	-	1	2	3	-
142	298151	D	31	18.66	1	3	1	1	7	1	-	-	1	2	3	-
143	831728	D	28	23.62	1	1	1	1	15	1	7.1	-	1	2	3	-
144	367906	D	47	31.23	1	3	1	2	8	1	13.3	-	1	2	1	-
145	612586	D	48	18.92	-	1	1	1	12	2	3.7	-	1	2	-	-
146	369873	D	30	14.04	1	3	1	1	8	1	-	-	1	2	3	-
147	821141	C	36	26.22	1	2	1	1	5	1	-	-	2	2	4	-
148	573910	D	33	24.69	1	2	2	2	8	1	7.8	-	1	2	3	-
149	629467	D	32	-	1	3	1	1	6	1	-	-	1	2	-	-
150	936802	D	40	-	-	1	1	1	5	2	8.4	-	1	2	-	-
151	66769	F	38	26.56	1	1	1	1	10	1	6.6	-	1	2	1	-
152	457991	C	35	28.62	1	4	1	1	5	1	14.1	-	1	2	2	-
153	703458	A	28	18.99	-	2	2	1	3	1	12.5	-	1	2	3	-
154	732813	D	46	25.54	1	4	1	1	4	1	-	-	1	2	1	-
155	827669	C	48	-	-	1	1	1	6	2	7.8	-	1	1	1	3
156	77218	C	38	26.11	-	2	2	1	3	1	-	-	1	2	-	-
157	954746	C	38	26.64	-	4	1	1	8	1	-	-	2	2	3	6
158	227822	D	38	-	-	3	2	1	3	2	-	-	1	2	2	6
159	55750	F	39	25.48	-	4	1	1	15	1	13.6	-	1	2	-	-
160	462875	D	33	24.34	-	2	1	1	8	2	-	-	1	2	3	-
161	834900	D	39	23.56	-	1	1	1	5	2	12.0	-	1	2	1	-
162	885587	D	39	-	1	3	1	1	15	1	11.8	13.0	1	1	1	-
163	40936	C	37	-	-	1	1	2	15	2	-	-	1	2	1	6
164	689016	D	48	27.77	-	1	1	1	5	2	11.9	-	1	1	1	3
165	691904	C	45	28.57	1	1	1	1	8	2	8.8	-	1	1	1	3

Sl no	hospital	no	Age	bmi	Interview	Reason	symptom	Cycles	Bleeding da	Dysmen	pre Hb	PostHb	USG	biopsy	Med Rx	improveme
166	298344	D	38	24.78	1	1	1	1	15	1	10.3	-	2	2	3	-
167	374670	D	37	23.31	3	4	2	1	3	1	-	-	1	2	3	-
168	846071	D	29	-	1	1	1	1	3	1	-	-	2	2	3	6
169	256697	D	38	-	-	4	1	2	5	2	10.7	-	1	1	1	6
170	977587	D	37	-	1	3	2	1	3	1	-	-	2	2	3	-
171	947264	D	34	-	-	4	1	1	15	2	-	10.7	1	2	3	12
172	784682	D	35	25.22	1	1	1	1	15	2	13.3	-	1	2	3	6
173	954157	D	42	-	-	1	1	1	5	2	9.3	12.4	1	1	-	-
174	834900	D	44	37.53	-	1	1	1	15	1	7.3	-	1	1	-	-
175	690023	D	38	26.64	1	1	1	1	15	2	3.2	-	2	2	-	-
176	527590	D	36	28.58	1	1	1	1	5	2	8.4	-	1	2	1	-
177	538985	D	37	-	1	1	1	1	5	2	8.5	-	1	2	-	-

Sl no	post insertr	Adv effect	Removal	Reason	Rem month	expulsion	expel.in mo	reinsertion	what tx	before	one	satisfacti	inference	SF phy.hea
1	3	2	-		2	-	-	-	20	0	7	3	100.00	100.00
2	3	2	-	-	2	-	-	-	-	-	5	2	90.00	100.00
3	3	2	-	-	1	25	2	2	70	20	4	1	100.00	100.00
4	1	2	-	-	2	-	-	-	80	10	7	3	45.00	100.00
5	1	2	-	-	2	-	-	-	100	0	7	3	80.00	100.00
6	2	2	-	-	2	-	-	-	100	0	7	3	80.00	100.00
7	-	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
8	1	2	-	-	1	24	2	1	-	-	5	2	100.00	0.00
9	3	2	-	-	2	-	-	-	-	-	7	3	80.00	50.00
10	2	1	3	14	2	-	2	2	60	40	5	2	70.00	0.00
11	-	2	-	-	2	-	-	-	80	0	7	3	100.00	100.00
12	3	2	-	-	2	-	-	-	-	-	6	3	45.00	75.00
13	1	2	-	-	2	-	-	-	100	30	2	1	75.00	0.00
14	1	2	-	-	2	-	-	-	80	20	-	-	75.00	100.00
15	1	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
16	3	2	-	-	2	-	-	-	100	0	7	3	90.00	100.00
17	3	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
18	1	2	-	-	2	-	-	-	90	20	7	3	100.00	100.00
19	-	2	-	-	2	-	-	-	-	-	-	3	-	-
20	1	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
21	3	2	-	-	2	-	-	-	100	20	7	3	85.00	100.00
22	1	2	-	-	2	-	-	-	50	0	7	3	100.00	100.00
23	1	2	-	-	2	-	-	-	80	0	7	3	90.00	100.00
24	-	2	-	-	2	-	-	-	100	25	6	3	100.00	75.00
25	1	1	3	12	2	-	-	-	100	50	5	2	95.00	100.00
26	-	1	3	40	2	-	-	-	-	-	5	2	80.00	50.00
27	-	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
28	-	2	-	-	2	-	-	-	70	30	6	3	50.00	100.00
29	-	2	-	-	1	27	2	2	100	0	7	3	100.00	100.00
30	-	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
31	3	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
32	3	2	-	-	2	-	-	-	-	-	7	3	75.00	100.00
33	1	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00

Sl no	post insertr	Adv effect	Removal	Reason	Rem month	expulsion	expel.in mo	reinsertion	what tx	before	one	satisfacti	inference	SF phy.hea
34	3	2	-	-	2	-	-	-	100	30	7	3	100.00	100.00
35	-	1	2	15	2	-	-	2	90	60	5	2	65.00	25.00
36	1	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
37	3	2	-	-	2	-	-	-	-	-	6	3	100.00	100.00
38	2	2	-	-	2	-	-	-	80	30	6	3	100.00	100.00
39	-	2	-	-	2	-	-	-	-	-	5	2	90.00	0.00
40	2	2	-	-	1	22	2	2	100	40	5	2	100.00	100.00
41	-	2	-	-	2	-	-	-	20	0	7	3	100.00	100.00
42	3	2	-	-	2	-	-	-	100	20	7	3	100.00	100.00
43	3	2	-	-	2	-	-	-	-	-	6	3	70.00	100.00
44	3	2	-	-	2	-	-	-	100	20	7	3	100.00	100.00
45	-	2	-	-	2	-	-	-	100	10	7	3	100.00	100.00
46	3	2	-	-	2	-	-	-	80	0	7	3	100.00	100.00
47	1	2	-	-	2	-	-	-	100	10	7	3	100.00	100.00
48	1	2	-	-	2	-	-	-	100	30	7	3	100.00	100.00
49	-	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
50	2	2	-	-	2	-	-	-	-	-	5	2	55.00	25.00
51	3	2	-	-	2	-	-	-	100	10	6	3	100.00	100.00
52	3	2	-	-	2	-	-	-	100	10	7	3	70.00	75.00
53	-	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
54	2	2	-	-	2	-	-	-	-	-	5	2	45.00	50.00
55	-	2	-	-	2	-	-	-	100	20	6	3	80.00	100.00
56	1	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
57	1	2	-	-	2	-	-	-	80	0	7	3	100.00	100.00
58	-	2	-	-	1	24	2	1	-	-	2	1	65.00	0.00
59	-	2	-	-	2	-	-	-	80	10	6	3	100.00	100.00
60	-	2	-	-	2	-	-	-	100	10	7	3	100.00	100.00
61	3	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
62	3	2	-	-	2	-	-	-	-	-	-	3	-	-
63	1	2	-	-	2	-	-	-	90	0	6	3	55.00	25.00
64	1	2	-	-	2	-	-	-	-	-	7	3	75.00	100.00
65	1	2	-	-	2	-	-	-	-	-	7	3	85.00	25.00
66	-	2	-	-	2	-	-	-	-	-	5	2	60.00	100.00

Sl no	post insertr	Adv effect	Removal	Reason	Rem month	expulsion	expel.in mo	reinsertion	what tx	before	one	satisfacti	inference	SF phy.hea
67	-	1	1	12	2	-	2	1	90	100	2	1	100.00	100.00
68	1	2	-	-	2	-	-	-	60	0	7	3	50.00	25.00
69	1	2	-	-	2	-	-	-	50	0	7	3	100.00	100.00
70	3	2	-	-	2	-	-	-	75	0	7	3	100.00	100.00
71	1	2	-	-	2	-	-	-	50	25	7	3	100.00	100.00
72	3	1	1	48	2	-	2	1	85	0	7	3	100.00	100.00
73	1	2	-	-	2	-	-	-	60	0	7	3	90.00	75.00
74	1	2	-	-	2	-	-	-	-	-	5	2	50.00	50.00
75	3	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
76	1	2	-	-	2	-	-	-	100	10	7	3	100.00	100.00
77	3	2	-	-	2	-	-	-	90	5	7	3	100.00	100.00
78	3	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
79	3	2	-	-	2	-	-	-	100	10	7	3	85.00	100.00
80	3	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
81	2	2	-	-	2	-	-	-	100	20	7	3	100.00	100.00
82	-	2	-	-	2	-	-	-	100	30	7	3	100.00	100.00
83	-	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
84	-	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
85	-	2	-	-	2	-	-	-	100	40	7	3	100.00	100.00
86	-	2	-	-	2	-	-	-	50	0	6	3	100.00	100.00
87	1	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
88	-	2	-	-	2	-	-	-	100	10	7	3	100.00	100.00
89	3	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
90	-	2	-	-	2	-	-	-	40	0	7	3	100.00	100.00
91	3	2	-	-	2	-	-	-	-	-	7	3	100.00	100.00
92	-	2	-	-	2	-	-	-	100	0	7	3	90.00	100.00
93	3	1	-	60	2	-	2	-	100	0	7	3	100.00	100.00
94	3	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
95	-	2	-	-	2	-	-	-	100	0	7	3	100.00	100.00
96	-	2	-	-	2	-	-	-	100	0	7	3	85.00	100.00
97	-	2	-	-	2	-	-	-	90	10	6	3	100.00	100.00
98	1	2	-	-	2	-	-	-	80	30	7	3	100.00	100.00
99	-	2	-	-	2	-	-	-	90	0	7	3	100.00	100.00

Sl no	post insertr	Adv effect	Removal	Reason	Rem month	expulsion	expel.in mo	reinsertion	what tx	before	one	satisfacti	inference	SF phy.hea
100	-	2	-	-	2	-	-	-	100	20	6	3	100.00	100.00
101	-	2	-	-	2	-	-	-	60	90	1	1	50.00	25.00
102	-	2	-	-	2	-	-	-	90	40	6	3	100.00	100.00
103	-	2	-	-	2	-	-	-	-	-	2	1	25.00	50.00
104	-	2	-	-	2	-	-	-	100	50	6	3	70.00	100.00
105	-	2	-	-	2	-	-	-	-	-	7	3	75.00	75.00
106	-	2	-	-	2	-	-	-	30	0	6	3	100.00	100.00
107	-	2	-	-	2	-	-	-	100	0	7	3	40.00	25.00
108	-	2	-	-	2	-	-	-	-	-	7	3	90.00	100.00
109	3	2	-	-	2	-	-	-	-	-	7	3	70.00	100.00
110	-	2	-	-	2	-	-	-	80	30	7	3	75.00	50.00
111	-	-	-	-	-	-	-	-	-	-	-	-	-	-
112	-	2	-	-	1	1	2	2	-	-	-	-	-	-
113	-	2	-	-	1	2	2	1	-	-	-	-	-	-
114	-	2	-	-	1	3	2	1	-	-	-	-	-	-
115	-	1	1	10	2	-	2	2	-	-	-	-	-	-
116	-	2	-	-	1	10	2	2	-	-	-	-	-	-
117	-	2	-	-	1	1	2	1	-	-	-	-	-	-
118	-	1	2	9	2	-	2	2	-	-	-	-	-	-
119	-	2	-	-	1	1	2	1	-	-	-	-	-	-
120	-	2	-	-	1	3	2	1	-	-	-	-	-	-
121	-	3	-	-	2	1	2	1	-	-	-	-	-	-
122	-	1	2	5	2	-	2	1	-	-	-	-	-	-
123	-	2	-	-	1	3	2	2	-	-	-	-	-	-
124	-	2	-	-	1	1	2	2	-	-	-	-	-	-
125	-	1	2	4	2	-	2	2	-	-	-	-	-	-
126	-	1	2	10	2	-	2	2	-	-	-	-	-	-
127	-	2	-	-	1	3	2	1	-	-	-	-	-	-
128	-	2	-	-	1	6	2	1	-	-	-	-	-	-
129	-	1	2	3	2	-	2	2	-	-	-	-	-	-
130	-	1	2	15	2	-	2	2	-	-	-	-	-	-
131	-	1	3	2	2	-	2	2	-	-	-	-	-	-
132	-	1	2	9	2	-	2	2	-	-	-	-	-	-

Sl no	post insertr	Adv effect	Removal	Reason	Rem month	expulsion	expel.in mo	reinsertion	what tx	before	one	satisfacti	inference	SF phy.hea
133	-	2	-	-	1	3	2	1	-	-	-	-	-	-
134	-	2	-	-	1	5	2	1	-	-	-	-	-	-
135	-	2	-	-	1	3	2	1	-	-	-	-	-	-
136	-	2	-	-	2	-	-	-	-	-	-	-	-	-
137	-	1	1	12	2	-	1	-	-	-	-	-	-	-
138	-	1	2	6	2	-	2	1	-	-	-	-	-	-
139	-	2	-	-	1	11	2	1	-	-	-	-	-	-
140	-	1	2	3	2	-	2	2	-	-	-	-	-	-
141	-	2	-	-	1	2	2	1	-	-	-	-	-	-
142	-	2	-	-	1	2	2	2	-	-	-	-	-	-
143	-	2	-	-	1	3	2	1	-	-	-	-	-	-
144	-	2	-	-	1	3	2	2	-	-	-	-	-	-
145	-	2	-	-	1	12	2	1	-	-	-	-	-	-
146	-	2	-	-	1	2	1	-	-	-	-	-	-	-
147	-	1	2	8	2	-	2	2	-	-	-	-	-	-
148	-	2	-	-	1	4	2	1	-	-	-	-	-	-
149	-	2	-	-	1	6	2	2	-	-	-	-	-	-
150	-	2	-	-	1	6	2	1	-	-	-	-	-	-
151	-	2	-	-	1	6	2	1	-	-	-	-	-	-
152	-	2	-	-	1	6	2	1	-	-	-	-	-	-
153	-	2	-	-	1	12	2	1	-	-	-	-	-	-
154	-	2	-	-	1	2	2	1	-	-	-	-	-	-
155	-	2	-	-	1	9	2	1	-	-	-	-	-	-
156	-	2	-	-	2	-	-	-	-	-	-	-	-	-
157	-	1	3	12	2	-	2	2	-	-	-	-	-	-
158	-	1	3	36	2	-	-	2	-	-	-	-	-	-
159	-	2	-	-	1	4	2	1	-	-	-	-	-	-
160	-	1	2	24	2	-	2	2	-	-	-	-	-	-
161	-	2	-	-	1	1	2	1	-	-	-	-	-	-
162	-	2	-	-	1	1	2	2	-	-	-	-	-	-
163	-	2	-	-	2	-	-	-	-	-	-	-	-	-
164	-	2	-	-	2	-	-	-	-	-	-	-	-	-
165	-	2	-	-	2	-	-	-	-	-	-	-	-	-

Sl no	post insertr	Adv effect	Removal	Reason	Rem month	expulsion	expel.in mo	reinsertion	what tx	before	one	satisfacti	inference	SF phy.hea
166	-	2	-	-	1	1	1	-	-	-	-	-	-	-
167	-	2	-	-	1	1	1	-	-	-	-	-	-	-
168	-	2	-	-	2	-	-	-	-	-	-	-	-	-
169	-	2	-	-	2	-	-	-	-	-	-	-	-	-
170	-	1	2	24	2	-	2	1	-	-	-	-	-	-
171	-	2	-	-	2	-	-	-	-	-	-	-	-	-
172	-	1	1	24	2	-	2	2	-	-	-	-	-	-
173	-	2	-	-	1	11	2	1	-	-	-	-	-	-
174	-	2	-	-	1	2	2	1	-	-	-	-	-	-
175	-	2	-	-	2	-	-	-	-	-	-	-	-	-
176	-	-	-	-	-	-	-	-	-	-	-	-	-	-
177	-	2	-	-	2	-	-	-	-	-	-	-	-	-

Sl no	SF Phy,h	Role emoti	Energy	Emotional	Social	Pain	Genhealth	UFS btotal	UFSatotal	.UFS sym.b	UFS sym a	HRQLTotal
1	100.00	85.00	92.00	100.00	100.00	90.00	121.00	36.00	22.00	9.00	99.00	27.00
2	0.00	40.00	48.00	25.00	100.00	70.00	111.00	46.00	18.00	8.00	93.00	38.00
3	100.00	65.00	88.00	100.00	90.00	90.00	76.00	53.00	15.00	15.00	61.00	38.00
4	100.00	75.00	80.00	100.00	100.00	55.00	123.00	39.00	22.00	9.00	101.00	30.00
5	100.00	85.00	100.00	100.00	100.00	95.00	156.00	40.00	27.00	11.00	129.00	29.00
6	100.00	75.00	84.00	100.00	90.00	95.00	103.00	37.00	21.00	8.00	zz	29.00
7	100.00	90.00	96.00	100.00	90.00	95.00	138.00	44.00	24.00	9.00	114.00	35.00
8	0.00	40.00	44.00	87.50	100.00	35.00	126.00	117.00	26.00	17.00	100.00	100.00
9	33.33	70.00	92.00	87.50	67.50	70.00	105.00	55.00	23.00	13.00	82.00	42.00
10	0.00	55.00	64.00	62.50	45.00	25.00	123.00	73.00	28.00	12.00	95.00	61.00
11	100.00	95.00	92.00	100.00	100.00	95.00	139.00	41.00	27.00	8.00	112.00	33.00
12	100.00	65.00	64.00	50.00	80.00	40.00	142.00	91.00	36.00	30.00	106.00	61.00
13	0.00	30.00	40.00	50.00	0.00	10.00	124.00	111.00	25.00	22.00	99.00	89.00
14	100.00	75.00	80.00	75.00	100.00	65.00	94.00	99.00	27.00	20.00	67.00	79.00
15	100.00	90.00	92.00	100.00	100.00	80.00	149.00	49.00	27.00	11.00	122.00	38.00
16	33.33	75.00	100.00	87.50	100.00	90.00	141.00	39.00	23.00	8.00	118.00	31.00
17	100.00	80.00	80.00	100.00	100.00	90.00	113.00	38.00	23.00	8.00	90.00	30.00
18	100.00	80.00	84.00	100.00	90.00	95.00	130.00	41.00	23.00	8.00	107.00	33.00
19	-	-	-	-	-	-	-	-	-	-	-	-
20	100.00	80.00	68.00	87.50	100.00	85.00	118.00	38.00	22.00	8.00	96.00	30.00
21	100.00	85.00	88.00	100.00	100.00	90.00	148.00	47.00	26.00	8.00	122.00	39.00
22	100.00	95.00	96.00	100.00	100.00	100.00	148.00	40.00	27.00	8.00	121.00	32.00
23	100.00	80.00	80.00	100.00	90.00	90.00	139.00	39.00	24.00	8.00	115.00	31.00
24	100.00	65.00	64.00	50.00	32.50	55.00	128.00	51.00	37.00	12.00	91.00	39.00
25	100.00	70.00	92.00	62.50	45.00	50.00	112.00	43.00	25.00	11.00	87.00	32.00
26	100.00	45.00	68.00	75.00	67.50	45.00	121.00	103.00	27.00	23.00	94.00	80.00
27	100.00	80.00	76.00	100.00	100.00	90.00	128.00	44.00	24.00	8.00	104.00	36.00
28	100.00	55.00	52.00	62.50	32.50	70.00	-	-	-	-	-	-
29	100.00	90.00	92.00	100.00	100.00	100.00	139.00	37.00	28.00	8.00	111.00	29.00
30	100.00	95.00	100.00	100.00	100.00	100.00	158.00	40.00	35.00	8.00	123.00	32.00
31	100.00	85.00	84.00	100.00	100.00	95.00	129.00	37.00	26.00	8.00	103.00	29.00
32	100.00	60.00	60.00	75.00	77.50	70.00	111.00	60.00	22.00	9.00	89.00	51.00
33	100.00	90.00	84.00	100.00	100.00	100.00	132.00	39.00	19.00	8.00	113.00	31.00

Sl no	SF Phy,h	Role emoti	Energy	Emotional	Social	Pain	Genhealth	UFS btotal	UFSatotal	.UFS sym.b	UFS sym a	HRQLTotal
34	100.00	90.00	88.00	100.00	100.00	85.00	129.00	38.00	24.00	9.00	105.00	29.00
35	33.33	70.00	80.00	62.50	90.00	40.00	127.00	128.00	21.00	21.00	106.00	107.00
36	100.00	85.00	80.00	100.00	100.00	85.00	124.00	39.00	24.00	8.00	100.00	31.00
37	100.00	80.00	88.00	100.00	90.00	100.00	76.00	43.00	19.00	8.00	57.00	35.00
38	100.00	80.00	72.00	100.00	100.00	85.00	133.00	42.00	20.00	10.00	113.00	32.00
39	0.00	25.00	4.00	50.00	0.00	45.00	104.00	83.00	29.00	18.00	75.00	65.00
40	100.00	85.00	84.00	100.00	90.00	95.00	135.00	89.00	25.00	16.00	110.00	73.00
41	100.00	90.00	88.00	100.00	100.00	95.00	148.00	40.00	29.00	8.00	119.00	32.00
42	100.00	90.00	88.00	100.00	100.00	75.00	156.00	41.00	30.00	10.00	126.00	31.00
43	100.00	75.00	76.00	100.00	77.50	75.00	128.00	41.00	22.00	8.00	106.00	33.00
44	100.00	80.00	84.00	100.00	90.00	85.00	137.00	43.00	24.00	9.00	113.00	34.00
45	100.00	75.00	80.00	100.00	100.00	80.00	122.00	47.00	21.00	9.00	101.00	38.00
46	100.00	65.00	76.00	100.00	100.00	85.00	112.00	39.00	22.00	8.00	90.00	31.00
47	100.00	80.00	84.00	100.00	100.00	95.00	118.00	45.00	19.00	11.00	99.00	34.00
48	100.00	75.00	84.00	100.00	100.00	90.00	115.00	42.00	20.00	8.00	95.00	34.00
49	100.00	90.00	76.00	100.00	100.00	90.00	145.00	38.00	26.00	8.00	119.00	30.00
50	66.67	80.00	60.00	75.00	45.00	35.00	71.00	44.00	16.00	9.00	55.00	35.00
51	100.00	80.00	80.00	100.00	100.00	90.00	127.00	42.00	22.00	8.00	105.00	34.00
52	100.00	40.00	64.00	62.50	75.00	55.00	124.00	90.00	33.00	23.00	91.00	67.00
53	100.00	85.00	84.00	100.00	100.00	95.00	133.00	44.00	23.00	8.00	110.00	36.00
54	33.33	15.00	28.00	100.00	35.00	45.00	103.00	86.00	22.00	17.00	81.00	69.00
55	100.00	100.00	80.00	87.50	90.00	95.00	162.00	62.00	29.00	11.00	133.00	51.00
56	100.00	90.00	84.00	100.00	90.00	95.00	142.00	49.00	25.00	12.00	117.00	37.00
57	100.00	90.00	92.00	100.00	100.00	100.00	-	-	-	-	-	-
58	0.00	40.00	48.00	25.00	100.00	35.00	142.00	160.00	27.00	30.00	115.00	130.00
59	100.00	60.00	72.00	100.00	77.50	70.00	120.00	72.00	23.00	16.00	97.00	56.00
60	100.00	90.00	92.00	100.00	100.00	90.00	-	-	-	-	-	-
61	100.00	80.00	84.00	100.00	77.50	85.00	130.00	40.00	23.00	8.00	107.00	32.00
62	-	-	-	-	-	-	64.00	-	25.00	-	39.00	-
63	66.67	35.00	28.00	87.50	45.00	20.00	144.00	87.00	27.00	16.00	117.00	71.00
64	66.67	95.00	92.00	87.50	90.00	90.00	141.00	84.00	24.00	24.00	117.00	60.00
65	33.33	95.00	92.00	50.00	10.00	65.00	131.00	44.00	31.00	11.00	100.00	33.00
66	100.00	60.00	52.00	87.50	55.00	100.00	73.00	61.00	18.00	16.00	55.00	45.00

Sl no	SF Phy,h	Role emoti	Energy	Emotional	Social	Pain	Genhealth	UFS btotal	UFSatotal	.UFS sym.b	UFS sym a	HRQLTotal
67	100.00	85.00	76.00	100.00	100.00	85.00	145.00	44.00	24.00	9.00	121.00	35.00
68	66.67	60.00	56.00	87.50	45.00	35.00	123.00	75.00	26.00	17.00	97.00	58.00
69	100.00	85.00	80.00	100.00	100.00	80.00	152.00	37.00	27.00	8.00	125.00	29.00
70	100.00	90.00	92.00	100.00	100.00	90.00	123.00	46.00	25.00	9.00	98.00	37.00
71	100.00	90.00	88.00	100.00	100.00	90.00	129.00	42.00	23.00	11.00	106.00	31.00
72	100.00	80.00	76.00	100.00	100.00	90.00	118.00	40.00	25.00	8.00	93.00	32.00
73	100.00	60.00	96.00	100.00	42.50	100.00	-	-	-	-	-	-
74	33.33	20.00	32.00	37.50	47.50	30.00	148.00	74.00	32.00	16.00	116.00	58.00
75	100.00	90.00	92.00	100.00	100.00	100.00	117.00	37.00	21.00	8.00	96.00	29.00
76	100.00	90.00	92.00	100.00	100.00	95.00	142.00	39.00	32.00	8.00	110.00	31.00
77	100.00	55.00	88.00	100.00	90.00	90.00	143.00	44.00	24.00	8.00	119.00	36.00
78	100.00	80.00	84.00	87.50	90.00	95.00	126.00	39.00	25.00	8.00	101.00	31.00
79	100.00	65.00	84.00	100.00	90.00	85.00	135.00	38.00	26.00	8.00	109.00	30.00
80	100.00	85.00	80.00	100.00	100.00	95.00	125.00	39.00	23.00	8.00	102.00	31.00
81	100.00	90.00	84.00	100.00	100.00	95.00	134.00	37.00	23.00	8.00	111.00	29.00
82	100.00	85.00	84.00	100.00	100.00	75.00	131.00	40.00	26.00	8.00	105.00	32.00
83	100.00	95.00	92.00	100.00	100.00	100.00	144.00	37.00	31.00	8.00	113.00	29.00
84	100.00	90.00	92.00	100.00	100.00	100.00	161.00	38.00	32.00	8.00	129.00	30.00
85	100.00	90.00	92.00	100.00	100.00	95.00	134.00	37.00	32.00	8.00	102.00	29.00
86	100.00	95.00	92.00	100.00	90.00	95.00	123.00	41.00	32.00	8.00	91.00	33.00
87	100.00	85.00	88.00	100.00	90.00	95.00	147.00	39.00	23.00	8.00	124.00	31.00
88	100.00	75.00	84.00	100.00	77.50	90.00	-	-	-	-	-	-
89	100.00	90.00	92.00	100.00	100.00	100.00	159.00	42.00	31.00	9.00	128.00	33.00
90	100.00	80.00	76.00	100.00	90.00	75.00	129.00	47.00	23.00	12.00	106.00	35.00
91	100.00	80.00	84.00	100.00	100.00	95.00	124.00	42.00	20.00	8.00	104.00	34.00
92	100.00	80.00	84.00	100.00	90.00	90.00	-	-	-	-	-	-
93	100.00	85.00	84.00	100.00	90.00	95.00	138.00	40.00	28.00	8.00	110.00	32.00
94	100.00	80.00	84.00	100.00	100.00	100.00	143.00	41.00	25.00	8.00	118.00	33.00
95	100.00	85.00	92.00	100.00	100.00	95.00	132.00	38.00	30.00	8.00	102.00	30.00
96	100.00	60.00	80.00	100.00	90.00	75.00	138.00	42.00	25.00	8.00	113.00	34.00
97	100.00	90.00	96.00	100.00	77.50	95.00	92.00	39.00	17.00	10.00	75.00	29.00
98	100.00	90.00	92.00	100.00	100.00	90.00	138.00	44.00	32.00	12.00	106.00	32.00
99	100.00	90.00	84.00	100.00	100.00	90.00	134.00	40.00	24.00	8.00	110.00	32.00

Sl no	SF Phy,h	Role emoti	Energy	Emotional	Social	Pain	Genhealth	UFS btotal	UFSatotal	.UFS sym.b	UFS sym a	HRQLTotal
100	100.00	80.00	72.00	100.00	90.00	70.00	-	-	-	-	-	-
101	0.00	20.00	36.00	0.00	12.50	25.00	159.00	149.00	38.00	38.00	121.00	111.00
102	100.00	70.00	88.00	100.00	90.00	60.00	-	-	-	-	-	-
103	66.67	40.00	20.00	87.50	22.50	20.00	145.00	115.00	28.00	17.00	117.00	98.00
104	0.00	10.00	36.00	12.50	45.00	40.00	133.00	88.00	25.00	15.00	108.00	73.00
105	100.00	80.00	76.00	100.00	90.00	95.00	113.00	82.00	34.00	21.00	79.00	61.00
106	100.00	85.00	88.00	100.00	100.00	90.00	143.00	40.00	29.00	8.00	114.00	32.00
107	100.00	70.00	72.00	50.00	45.00	40.00	156.00	48.00	30.00	17.00	126.00	31.00
108	100.00	75.00	96.00	100.00	90.00	70.00	159.00	39.00	30.00	9.00	129.00	30.00
109	100.00	15.00	16.00	50.00	22.50	40.00	119.00	80.00	25.00	12.00	94.00	68.00
110	33.33	80.00	64.00	87.50	100.00	85.00	92.00	74.00	20.00	15.00	72.00	59.00
111	-	-	-	-	-	-	-	-	-	-	-	-
112	-	-	-	-	-	-	-	-	-	-	-	-
113	-	-	-	-	-	-	-	-	-	-	-	-
114	-	-	-	-	-	-	-	-	-	-	-	-
115	-	-	-	-	-	-	-	-	-	-	-	-
116	-	-	-	-	-	-	-	-	-	-	-	-
117	-	-	-	-	-	-	-	-	-	-	-	-
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132	-	-	-	-	-	-	-	-	-	-	-	-

Sl no	SF Phy,h	Role emoti	Energy	Emotional	Social	Pain	Genhealth	UFS btotal	UFSatotal	.UFS sym.b	UFS sym a	HRQLTotal
133	-	-	-	-	-	-	-	-	-	-	-	-
134	-	-	-	-	-	-	-	-	-	-	-	-
135	-	-	-	-	-	-	-	-	-	-	-	-
136	-	-	-	-	-	-	-	-	-	-	-	-
137	-	-	-	-	-	-	-	-	-	-	-	-
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162	-	-	-	-	-	-	-	-	-	-	-	-
163	-	-	-	-	-	-	-	-	-	-	-	-
164	-	-	-	-	-	-	-	-	-	-	-	-
165	-	-	-	-	-	-	-	-	-	-	-	-

Sl no	SF Phy,h	Role emoti	Energy	Emotional	Social	Pain	Genhealth	UFS btotal	UFSatotal	.UFS sym.b	UFS sym a	HRQLTotal
166	-	-	-	-	-	-	-	-	-	-	-	-
167	-	-	-	-	-	-	-	-	-	-	-	-
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169	-	-	-	-	-	-	-	-	-	-	-	-
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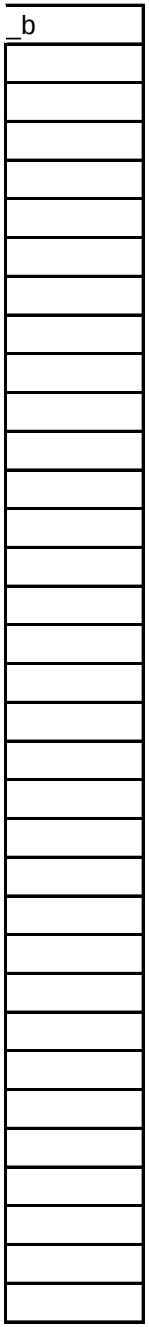
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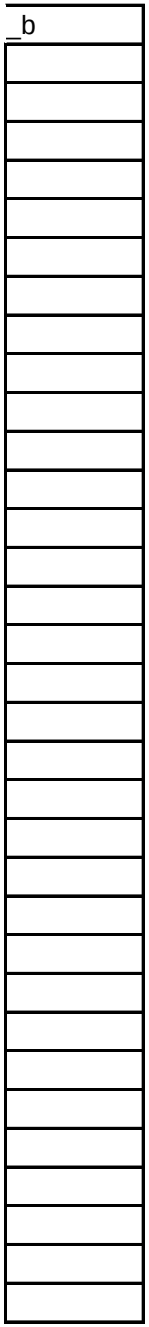
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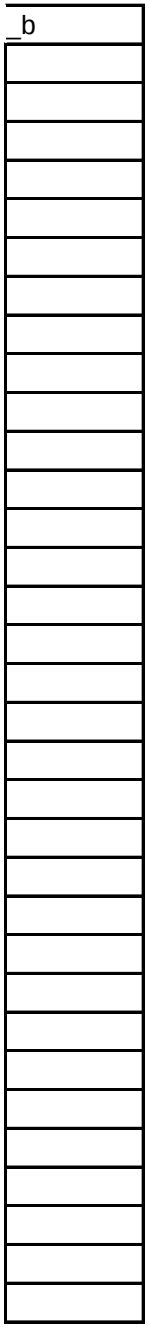
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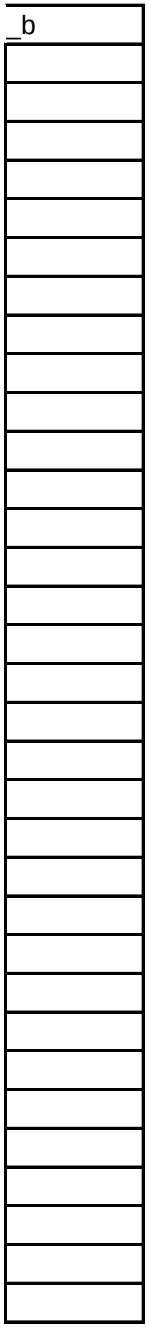
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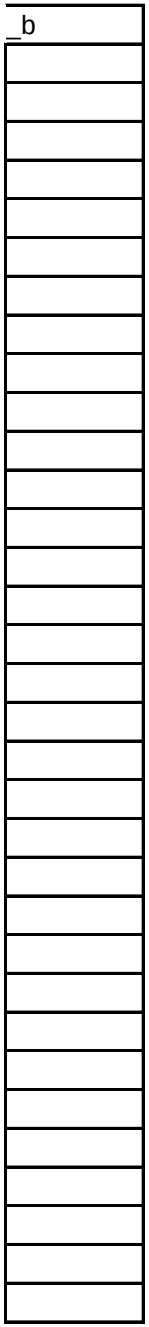
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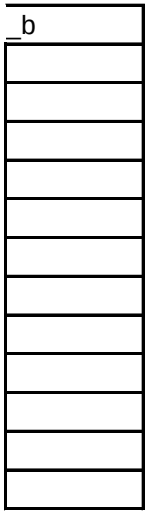
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ABBREVIATIONS

AUB – Abnormal uterine bleeding

DNA – Deoxy ribonucleic acid

DUB – Dysfunctional uterine bleeding

FIGO – *Fédération Internationale de Gynécologie et d'Obstétrique* (International Federation of Obstetrics and Gynaecology)

GnRh – Gonadotrophin releasing hormone

HMB – Heavy menstrual bleeding

LNG-IUS – Levonorgesterel intrauterine system

NSAIDs- Non steroidal anti inflammatory drug

OCP- Oral contraceptive pill

PBAC- Pictorial blood loss assessment chart

PG – Prostaglandin

RBC – Red blood cell

SLE – Systemic Lupus erythematoses

TCRE – Transcervical resection of the endometrium

ANNEXURES

ANNEXURE I

INFORMED CONSENT

Christian Medical College, Vellore

Department of obstetrics & Gynecology

Participant Information sheet

Study on follow up of patients on MIRENA inserted at CMC VELLORE,

You are being requested to participate in a study to see **the effectiveness of inserting MIRENA in the medical management of excessive bleeding during menstrual cycles and to study the improvement in the Health Related Quality of Life**. We hope to include about 300 people in this study.

What is the need for the study ?

Heavy menstrual bleeding is a common problem in women of reproductive age. It is expensive to treat and can severely affect the woman's quality of life. Many women are not happy with the medical treatment and prefer surgery. MIRENA is the non surgical alternative , which is reversible and spares childbearing. Studies have proved that MIRENA is safe and equally effective for all age group of women, improving the quality of life. Even in our hospital many women benefit from the insertion of MIRENA, which is yet to be studied. If you are part of this study, and if the beneficial effects are proven, it will benefit many other women, and help them to decide not to have hysterectomy(removal of uterus)

Is there a harm to you in participating in the study?

There will be no harm to you during participation in the study. The standard routine care will continue independent of the study result.

If you take part what will you have to do?

If you agree to participate in this study, you will be mailed a set of questionnaire which has to be answered, in relation to your bleeding pattern during menstrual cycle, the associated symptoms, the health problems faced, before insertion of MIRENA and then to follow up with the improvement of symptoms, and the quality of life after insertion of MIRENA. No additional procedures will be conducted for this study.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

Will you have to pay for the study ?

NO payment required for the study. The postal charges will be paid by us. Any other treatment that you usually take will continue and the routine charges for the treatment will be paid by you.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please ask Dr.Latha Lakshmi, Dr.Alice George(tel: 9994629053 or email to og1@cmcvellore.ac.in

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title: Study of Follow up of Patients on MIRENA INSERTION

Study Number:

Participant's name:

Date of Birth / Age (in years):

I_____

_____, wife of _____

(Please tick boxes)

Declare that I have read the information sheet provided to me regarding this study and have clarified any doubts that I had. [ ]

I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]

I also understand that neither I, nor my doctors, will have any knowledge of the result during the study[ ]

I understand that I will not be charged anything under the study[ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree to take part in this study [ ]

Name:

Signature:

Date:

Name of witness:

Relation to participant:

Date:

Annexure II

GENERAL PROFORMA

GP 1)Name :- 2) Hospital No -

3)Husband's name:- 4) I.D No -

5) Patient's age / Date of Birth- 6) Telephone No-

7)Reason for insertion 8) e mail id-

9)Date of insertion

GP 10)Indication for MIRENA:-1) Menorrhagia ( )

2) Dysmenorrhea ( )

3) Dyspareunia ( )

4) Contraception( )

5) Endometrial Hyperplasia( )

11) Parity- a)P ( ) b) L ( )

12) Menstrual History a) Prior menstrual periods :- Regular(1) /Irregular(2)

b) EXCESSIVE FLOW: Yes(1)/ No(2)

c) No of days – 1) < 3 days 2) 3 – 5 days 3) 5- 8 days 4) > 8 days

13) Dysmenorrhea – Yes(1)/ No(2)

14) Pre insertion Hb ( ) gm%

15)

1

	YES(1)	NO(2)
a-Treatment of anemia		
b-Iron supplements		
c- Thyroid disorder		
d-Ultrasound screening done		

16)U/S Report -

17)Endometrial biopsy done - Yes(1) / No (2)

18)Bx Report –

GP 19) In addition to Mirena

1)Used Progesterones – Yes(1) / No(2)

2)Used NSAIDs/ Tranexemic acid –Yes (1) / No (2)

3) Used OCPs – Yes (1)/ No (2)

4) Used Danazol/ GnRh – Yes (1) /No(2)

20) Post insertion Hb – Yes (1) / No (2)

21) If Yes Hb - gm%

22) Bleeding symptoms – 1)Improved after 3 cycles

2) Improved after 6 cycles

3) Improved after 1 year

GP 23) SURVIVAL ANALYSIS

1) Voluntary Removal of Mirena - Yes (1) / No(2)
2) If Yes – Reason for removal
3) If Yes – After how many years
4) Spontaneous EXPULSION – Yes (1) / No (2)
5) If Yes – After how many years
6) If Yes – Was it Reinserted – Yes (1) /No(2)

ANNEXURE III

APPENDIX A

Pt. Initials: _____ Pt. ID: _____

Date: _____

UTERINE FIBROID SYMPTOM AND HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE (UFS-QOL)

Listed below are symptoms experienced by women who have uterine fibroids. Please consider each symptom as it relates to your uterine fibroids or menstrual cycle. Each question asks how much distress you have experienced from each symptom during the previous 3 months.

There are no right or wrong answers. Please be sure to answer every question by checking (✓) the most appropriate box. If a question does not apply to you, please mark "not at all" as a response.

During the previous 3 months, how distressed were you by...	Not at all	A little bit	Some-what	A great deal	A very great deal
1. Heavy bleeding during your menstrual period	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. Passing blood clots during your menstrual period	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. Fluctuation in the duration of your menstrual period compared to your previous cycle	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. Fluctuation in the length of your monthly cycle compared to your previous cycles	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. Feeling tightness or pressure in your pelvic area	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. Frequent urination during the daytime hours	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. Frequent nighttime urination	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. Feeling fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following questions ask about your feelings and experiences regarding the impact of uterine fibroid symptoms on your life. Please consider each question as it relates to your experiences with uterine fibroids during the previous 3 months.

There are no right or wrong answers. Please be sure to answer every question by checking (✓) the most appropriate box. If the question does not apply to you, please check "none of the time" as your option.

During the previous 3 months, how often have your symptoms related to uterine fibroids...	None of the time	A little of the time	Some of the time	Most of the time	All of the time
9. Made you feel anxious about the unpredictable onset or duration of your periods?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. Made you anxious about traveling?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11. Interfered with your physical activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12. Caused you to feel tired or worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
13. Made you decrease the amount of time you spent on exercise or other physical activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. Made you feel as if you are not in control of your life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. Made you concerned about soiling underclothes?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. Made you feel less productive?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
17. Caused you to feel drowsy or sleepy during the day?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18. Made you feel self-conscious of weight gain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19. Made you feel that it was difficult to carry out your usual activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20. Interfered with your social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21. Made you feel conscious about the size and appearance of your stomach?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22. Made you concerned about soiling bed linen?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the previous 3 months, how often have your symptoms related to uterine fibroids...	None of the time	A little of the time	Some of the time	Most of the time	All of the time
23. Made you feel sad, discouraged, or hopeless?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
24. Made you feel down hearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
25. Made you feel wiped out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26. Caused you to be concerned or worried about your health?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27. Caused you to plan activities more carefully?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28. Made you feel inconvenienced about always carrying extra pads, tampons, and clothing to avoid accidents?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
29. Caused you embarrassment?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30. Made you feel uncertain about your future?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31. Made you feel irritable?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32. Made you concerned about soiling outer clothes?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33. Affected the size of clothing you wear during your periods?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34. Made you feel that you are not in control of your health?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35. Made you feel weak as if energy was drained from your body?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
36. Diminished your sexual desire?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
37. Caused you to avoid sexual relations?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

ANNEXURE IV

SF 36

ANNEXURE V

PATIENT NAME

ID NUMBER

HOSPITAL NUMBER

PLEASE INDICATE YOUR SUBJECTIVE LEVEL OF ENDOMETRIOSIS PAIN

A) BEFORE INSERTION

VISUAL ANALOG SCALE(VAS)

0----------100

ABSENCE UNBEARABLE

OF PAIN PAIN

0--- 10---20---30---40---50---60---70---80---90---100

B) AFTER INSERTION

VISUAL ANALOG SCALE(VAS)

0----------100

ABSENCE UNBEARABLE

OF PAIN PAIN

0--- 10---20---30---40---50---60---70---80---90---100

ANNEXURE VI

CLINICAL GLOBAL IMPRESSIONS SCALE

PATIENT NAME

ID NUMBER

HOSPITAL NUMBER

CLINICAL GLOBAL IMPRESSIONS SCALE (CGI SCALE – GLOBAL IMPROVEMENT ITEM)

7 --- VERY MUCH SATISFIED

6 --- MUCH SATISFIED

5 --- MINIMALLY SATISFIED

4 --- NEITHER SATISFIED NOR DISSATISFIED

3 --- MINIMALLY DISSATISFIED

2 --- MUCH DISSATISFIED

1 --- VERY MUCH DISSATISFIED

INFERENCE

6 & 7 ----- SATISFIED

5 ------ MINIMALLY SATISFIED

1 – 4 ------ UNDECIDED OR WORSE